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**Herbowy et al.**

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(54) **INTRA-VAGINAL DEVICE FOR FECAL INCONTINENCE**

USPC ..... 600/29-32, 37; 128/830, 834-836, 885, 128/DIG. 25

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See application file for complete search history.

(73) Assignee: **Pelvalon, Inc.**, Sunnyvale, CA (US)

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 263 days.

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This patent is subject to a terminal disclaimer.

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(22) PCT Filed: **Mar. 16, 2011**

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(86) PCT No.: **PCT/US2011/028691**

§ 371 (c)(1),

(2), (4) Date: **Sep. 17, 2012**

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**Related U.S. Application Data**

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(51) **Int. Cl.**

**A61F 2/00** (2006.01)

**A61F 6/08** (2006.01)

(52) **U.S. Cl.**

CPC ..... **A61F 2/0009** (2013.01); **A61F 2/0013** (2013.01); **A61F 2/005** (2013.01); **A61F 6/08** (2013.01)

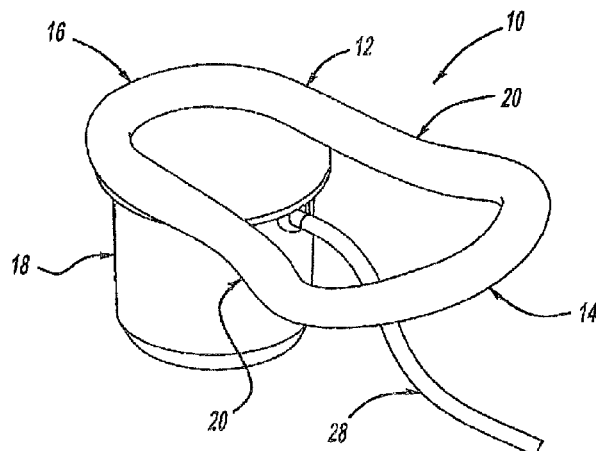
(58) **Field of Classification Search**

CPC ..... A61F 2/0004; A61F 2/005; A61F 2/0009; A61F 2/0013; A61F 2/0027; A61F 6/08; A61F 2/0022; A61F 2/0031; A61B 17/12022; A61B 2/0004; A61B 2/0009; A61B 2/0013; A61B 2/0027; A61B 6/08; A61B 17/42

(57) **ABSTRACT**

An intra-vaginal device for the control of stool passage, including a body mechanism for securing the device around the area of the pubic notch and in the area of the posterior fornix, the body mechanism including a force applying mechanism for reversibly applying a force to a posterior portion of the vagina to occlude the rectum. A method of controlling the passage of stool in a patient, by inserting an intra-vaginal device into the patient's vagina such that an anterior end rests around the pubic notch and a posterior end rests in the posterior fornix, exerting a force towards the posterior side of the vagina, moving an anterior wall of the patient's rectum towards the posterior wall of the rectum with the force applying portion, impeding the passage of stool, and removing the force, allowing stool to pass.

**41 Claims, 41 Drawing Sheets**



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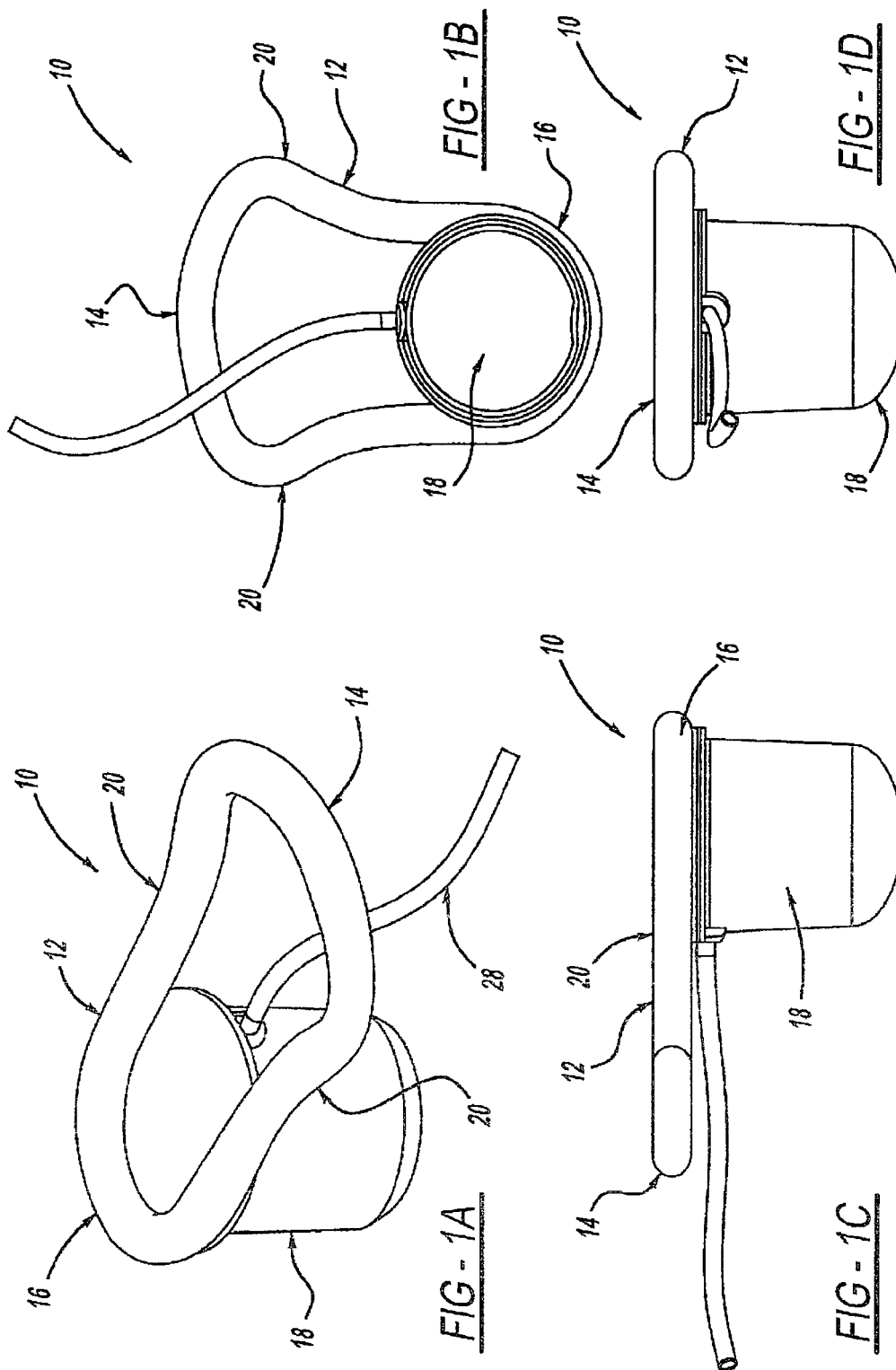
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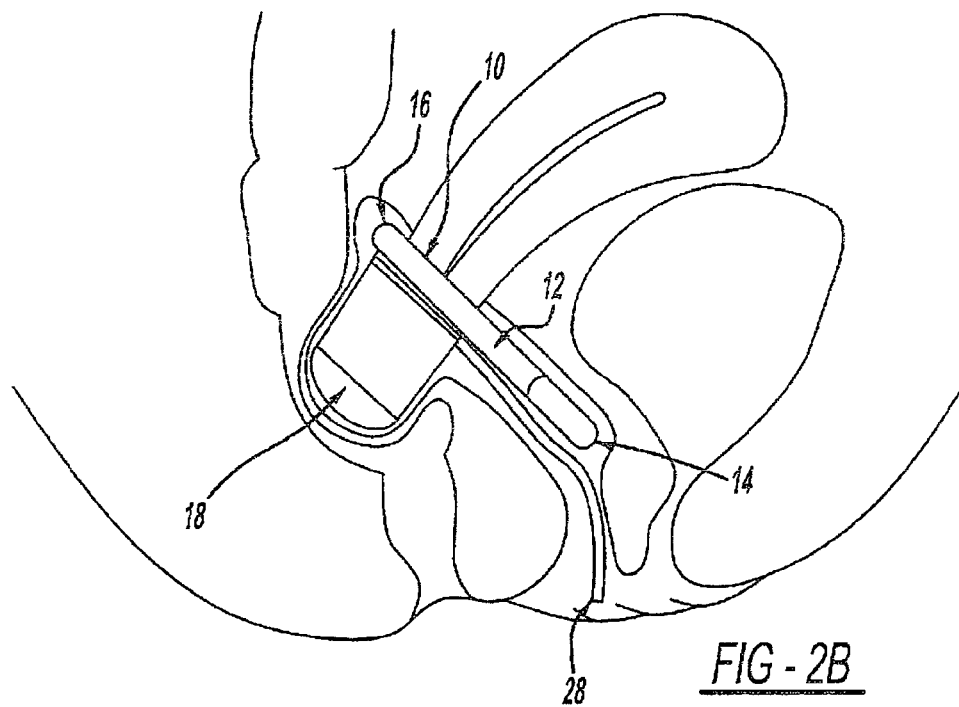
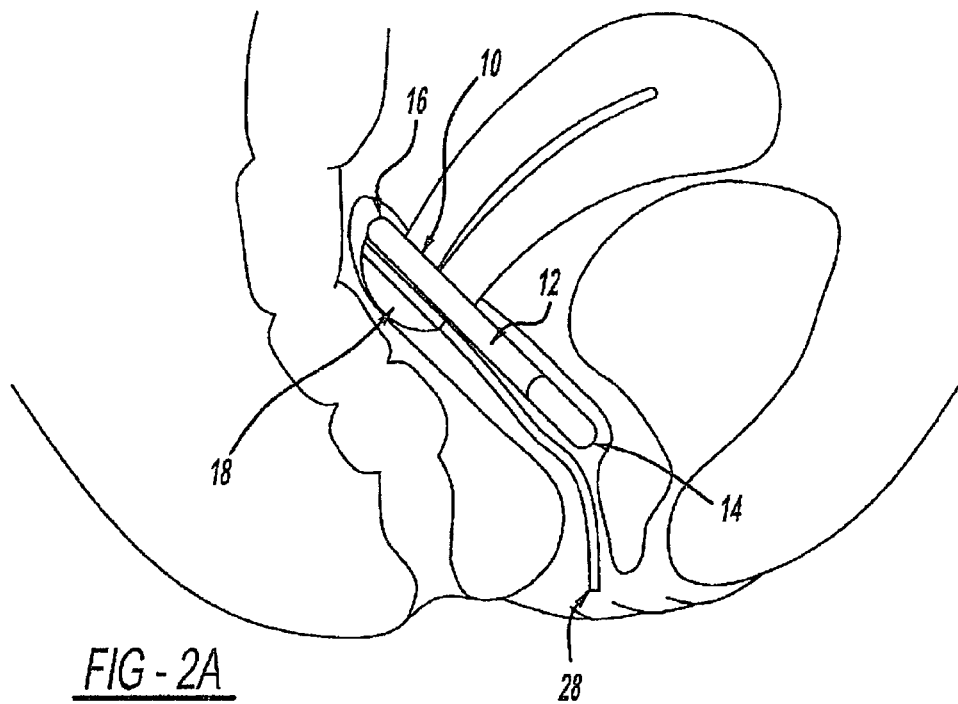
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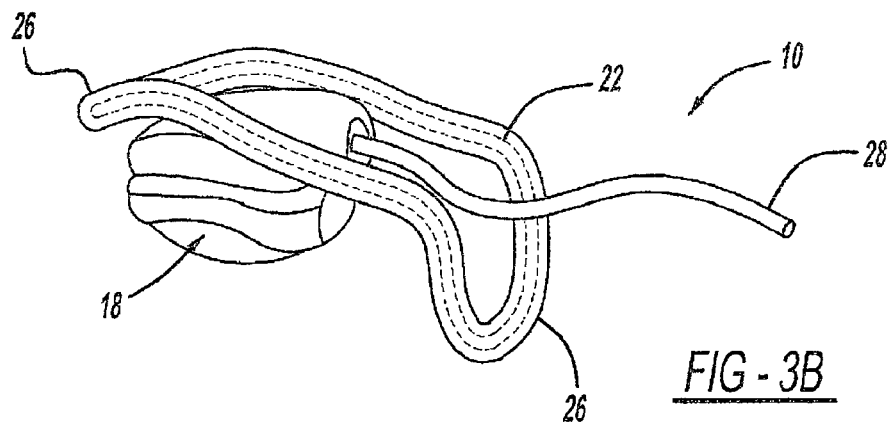
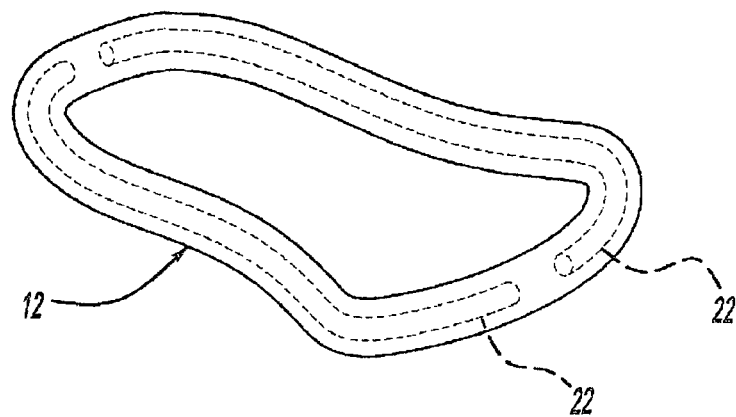
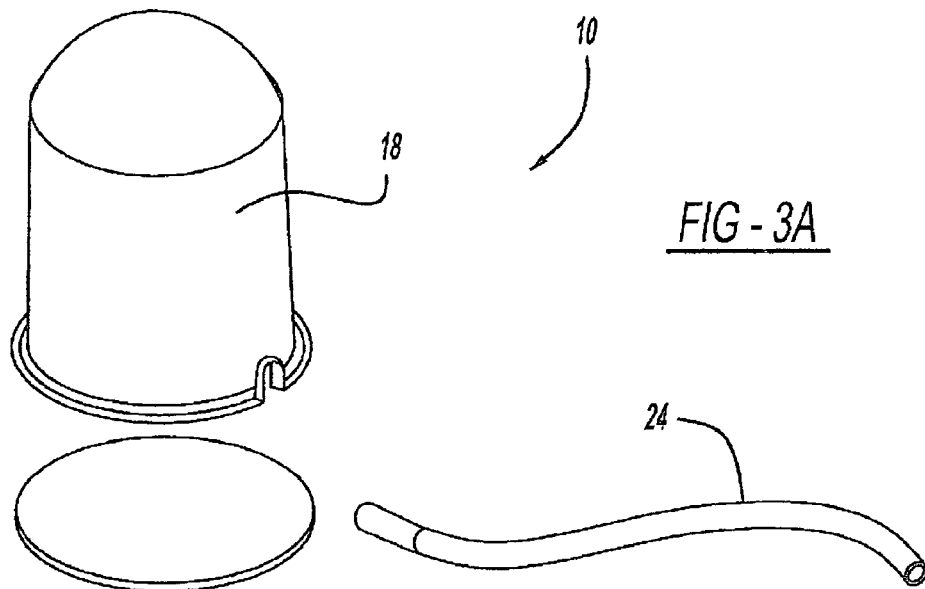
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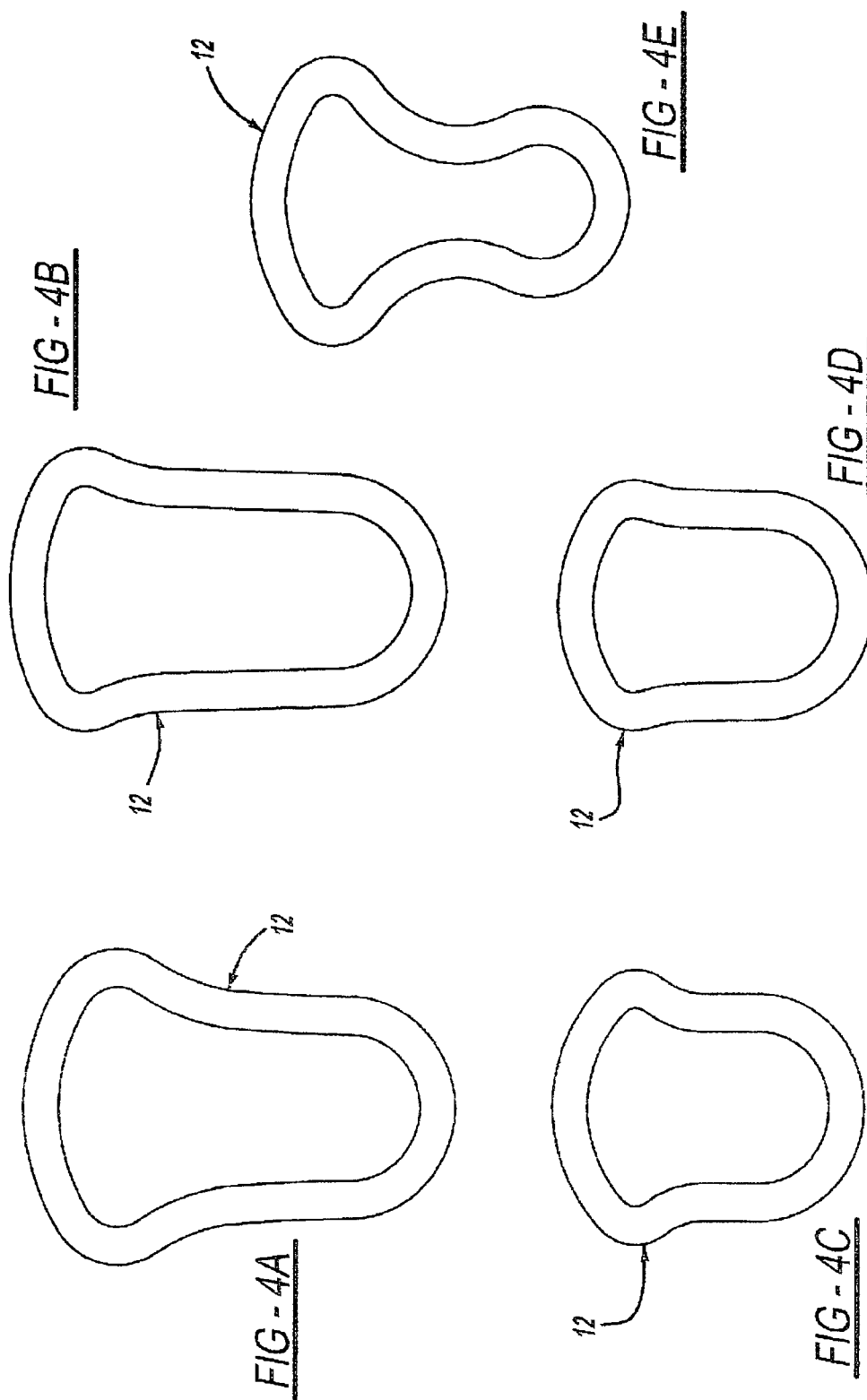
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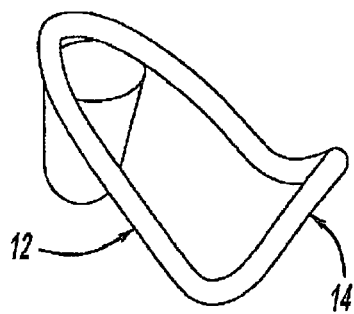


FIG - 5A

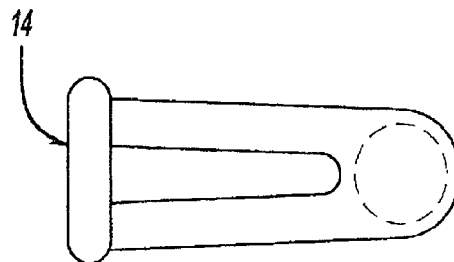


FIG - 5B

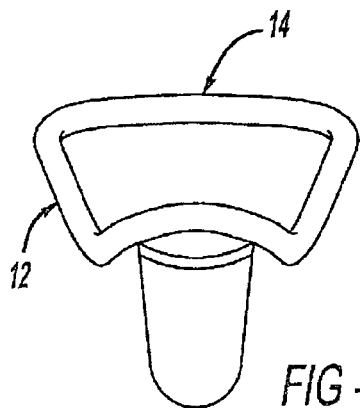


FIG - 5C

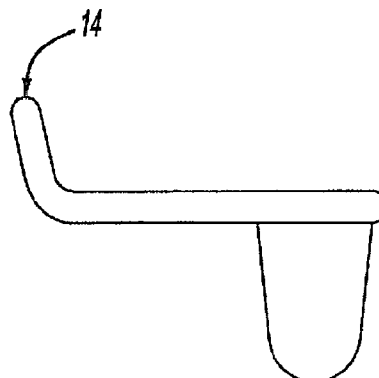


FIG - 5D

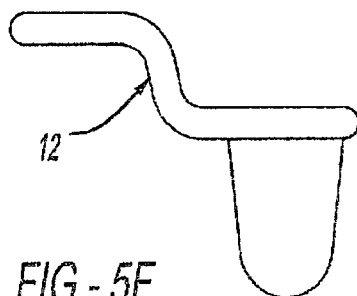


FIG - 5F

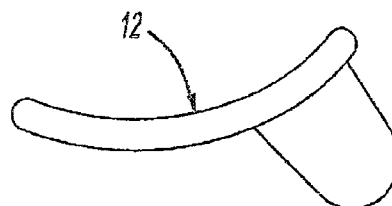


FIG - 5G

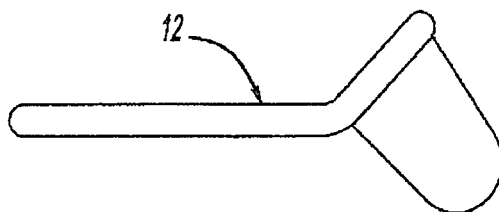


FIG - 5I



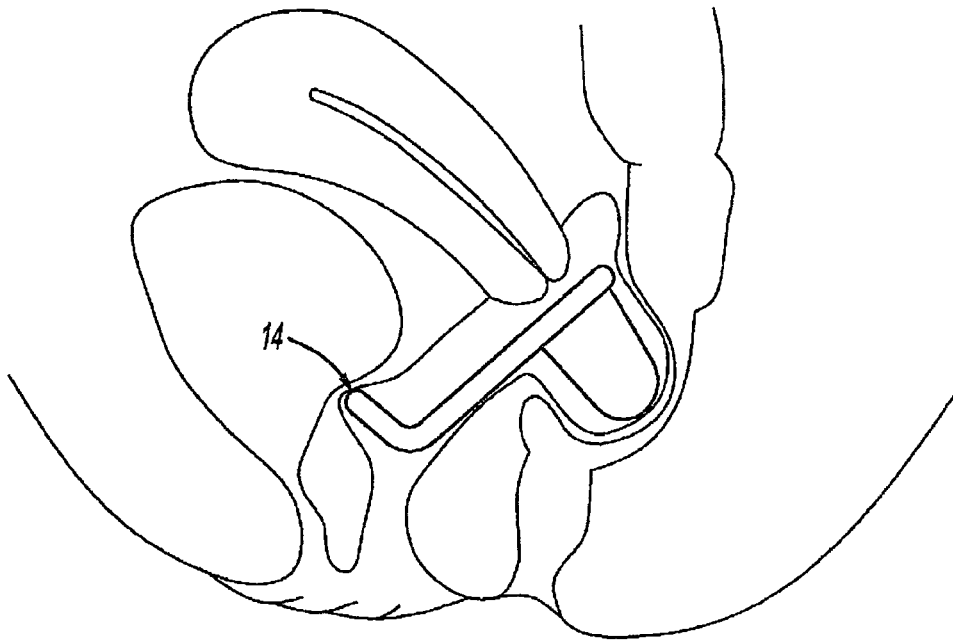


FIG - 5E

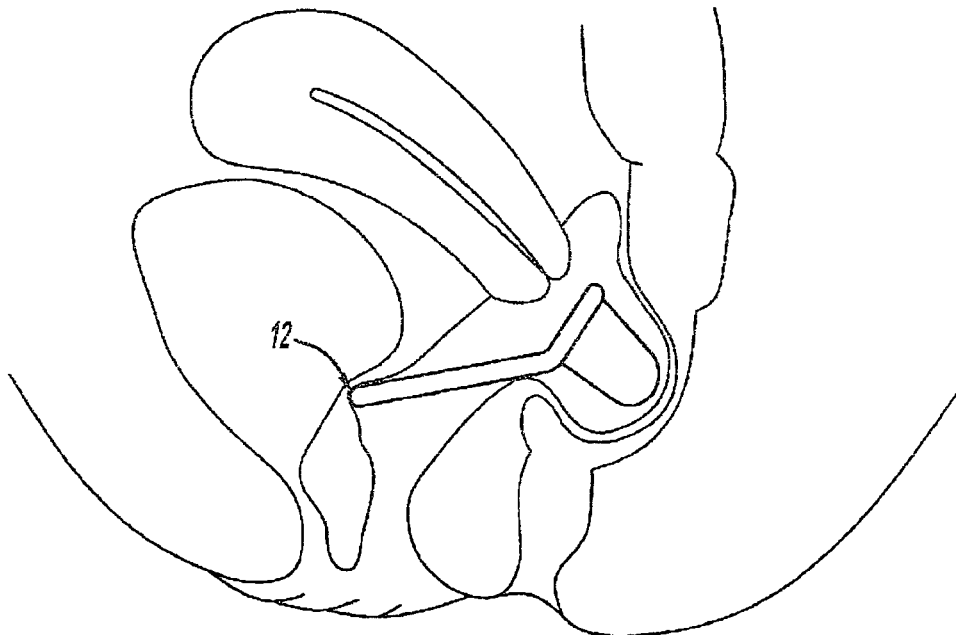
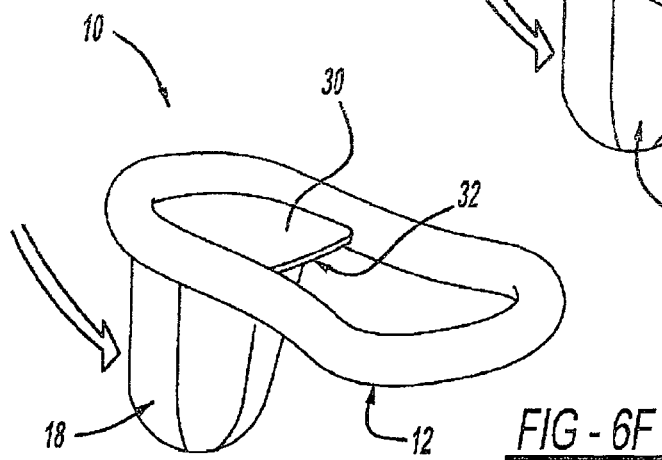
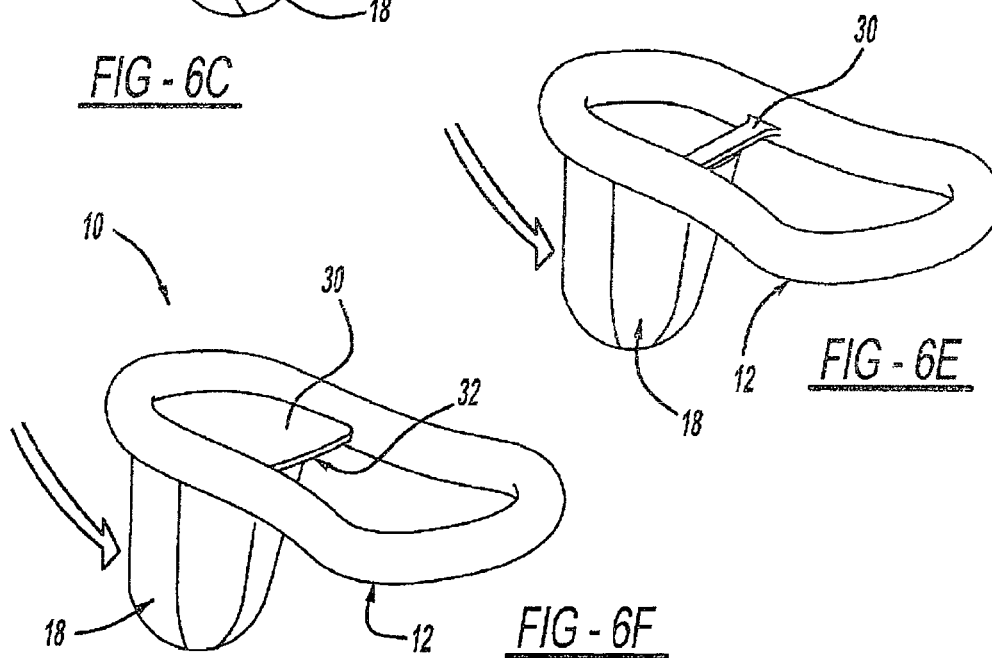
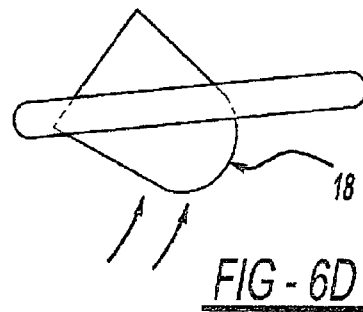
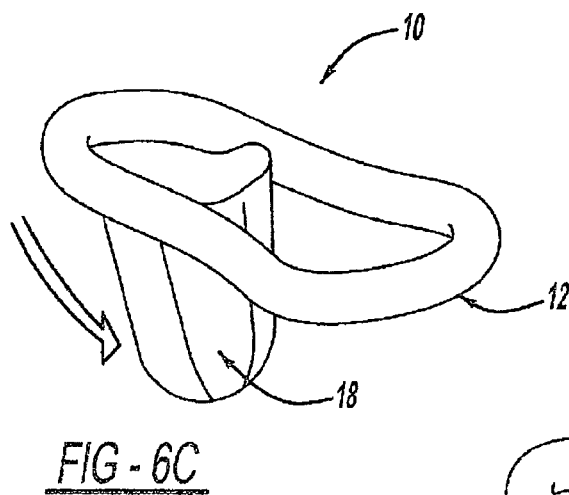
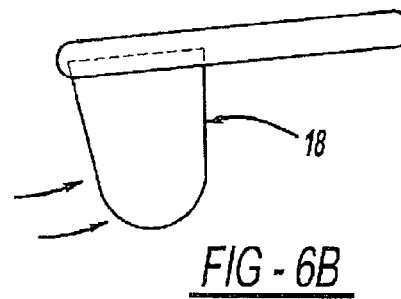
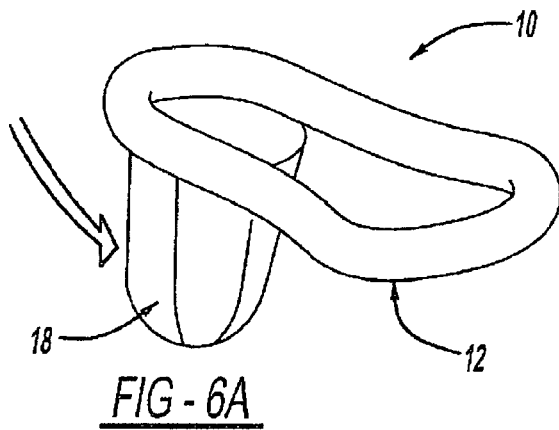


FIG - 5H



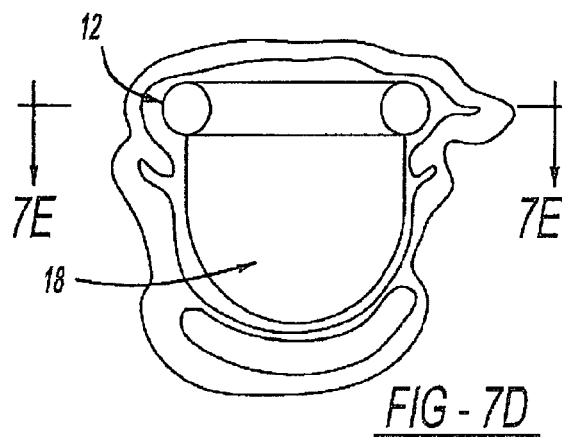
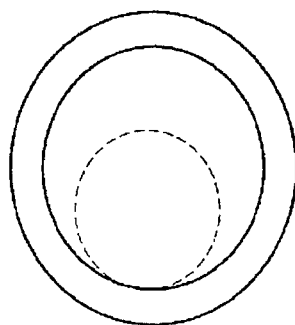
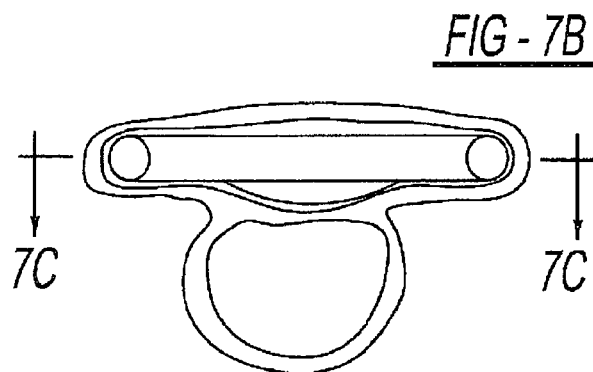
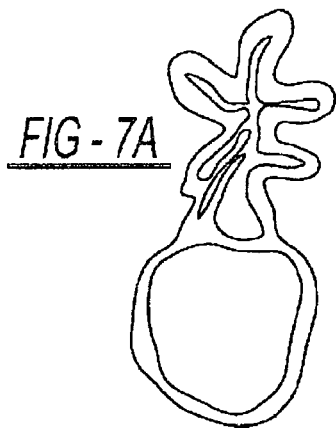
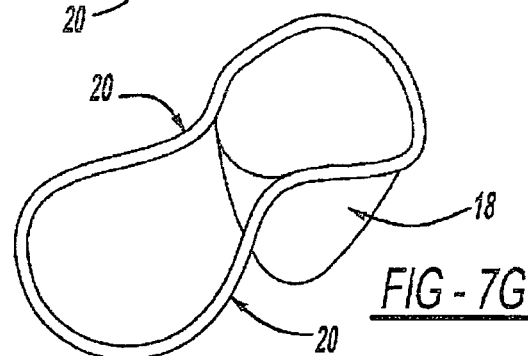
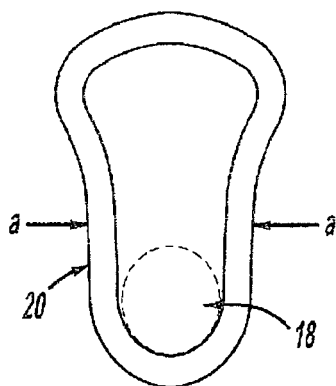
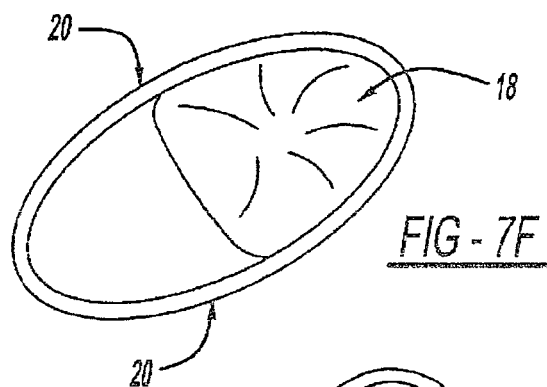
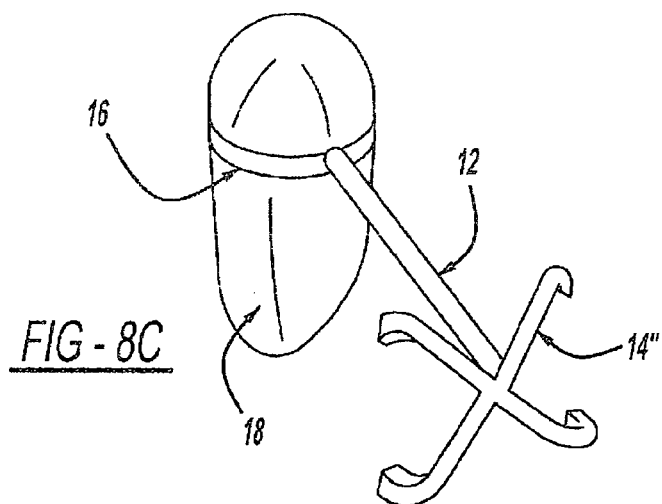
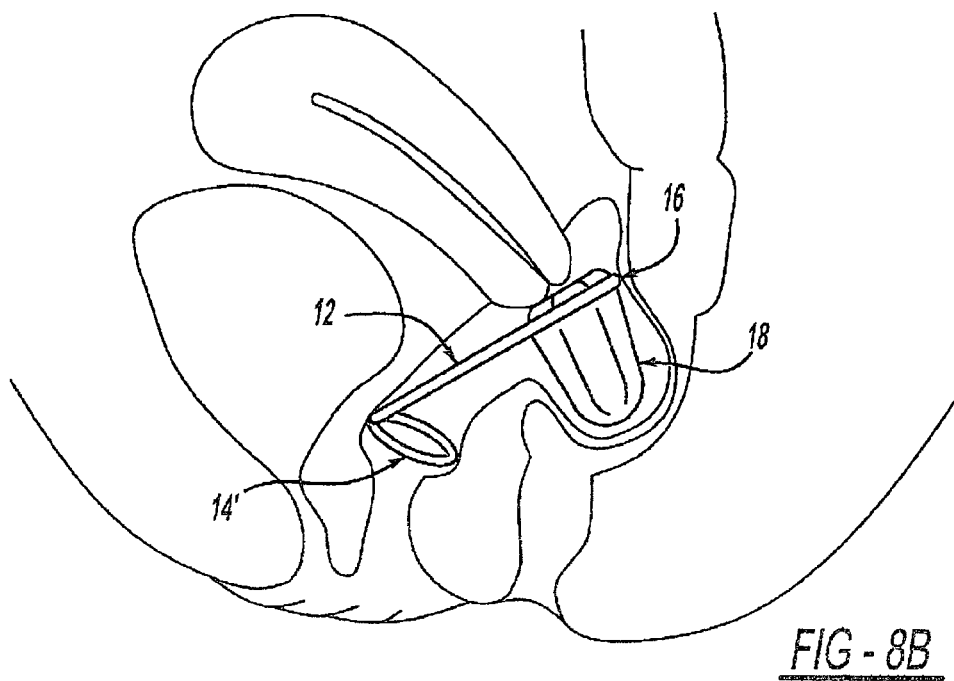
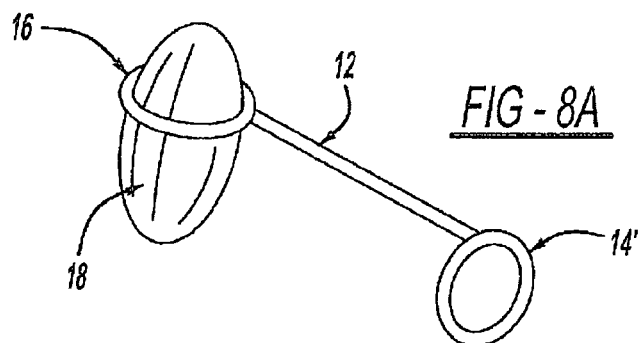
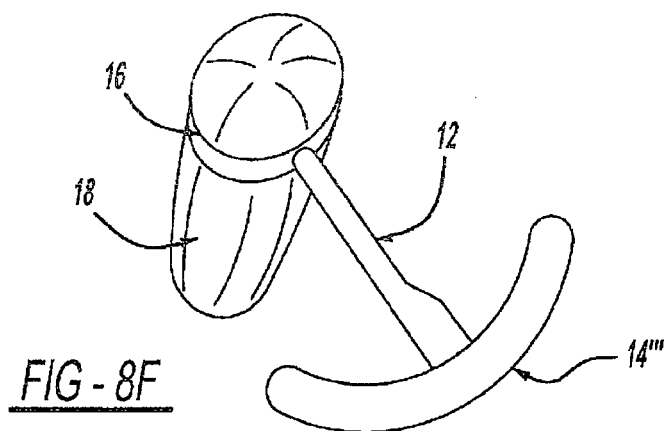
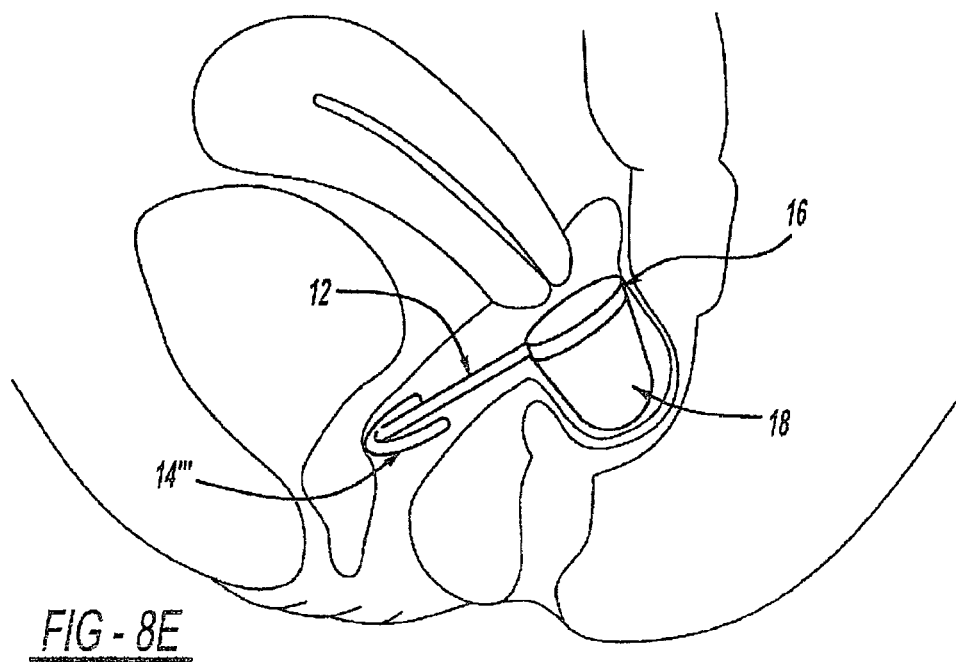
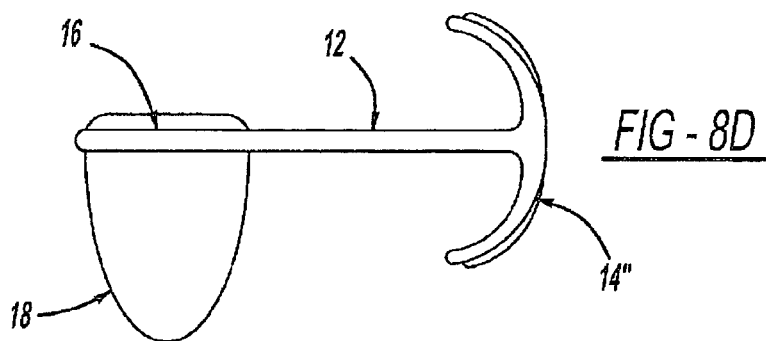
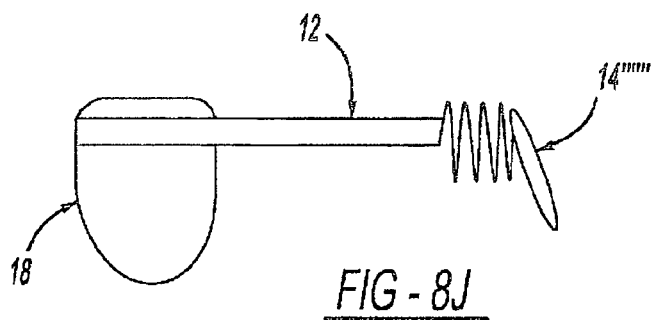
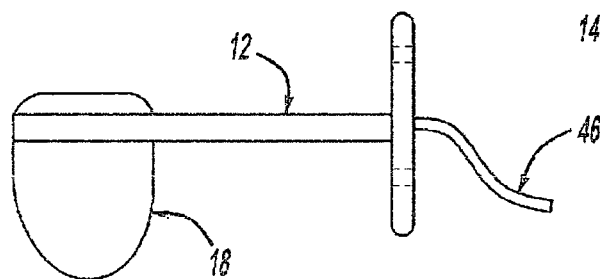
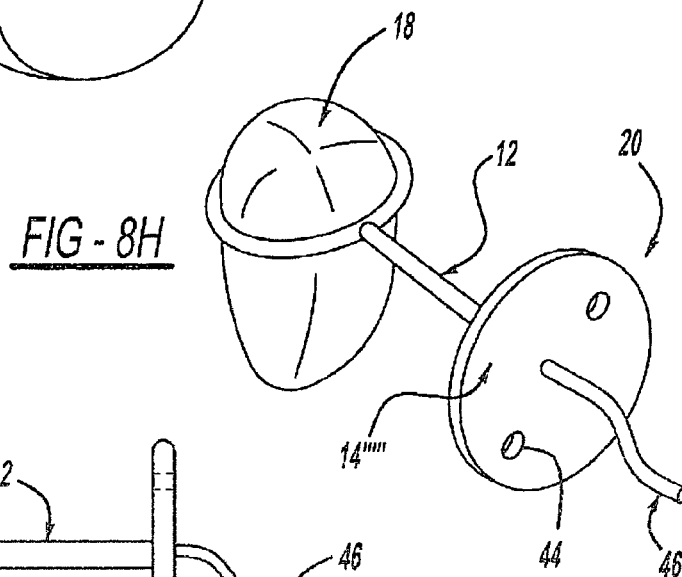
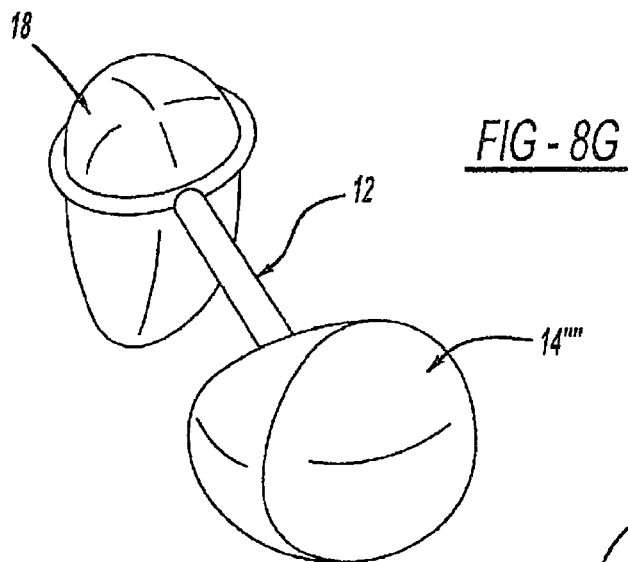


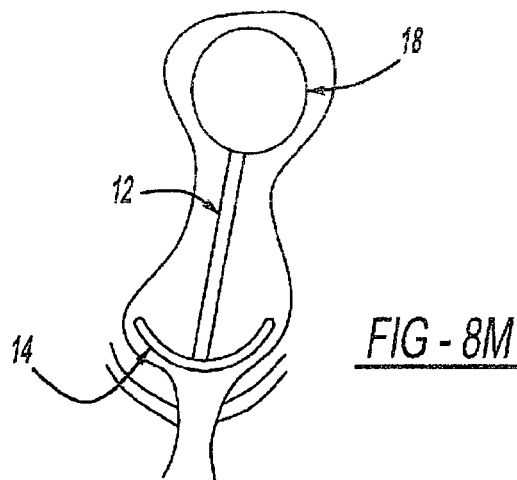
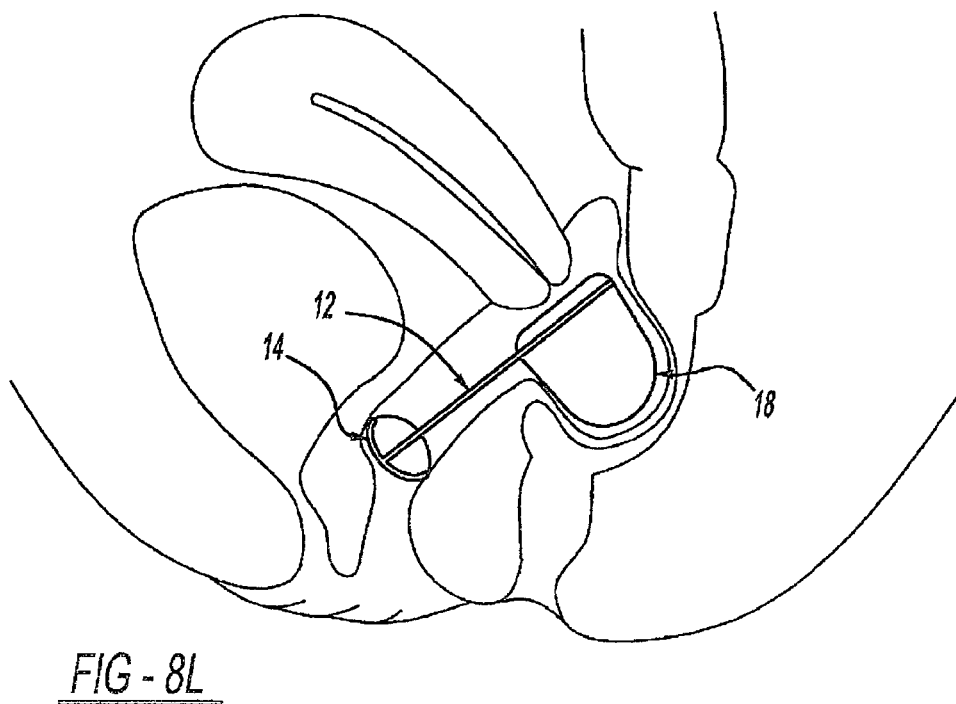
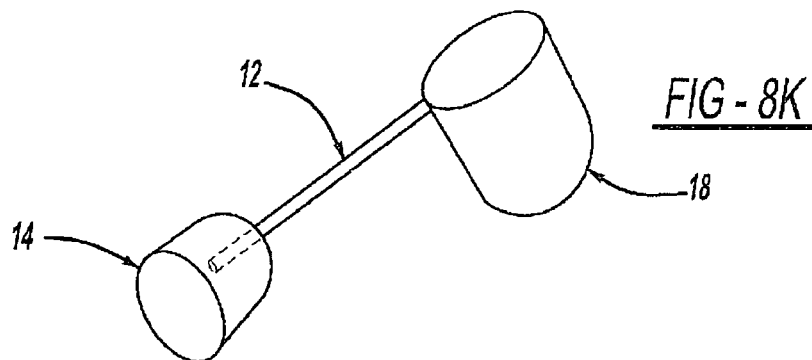
FIG - 7C

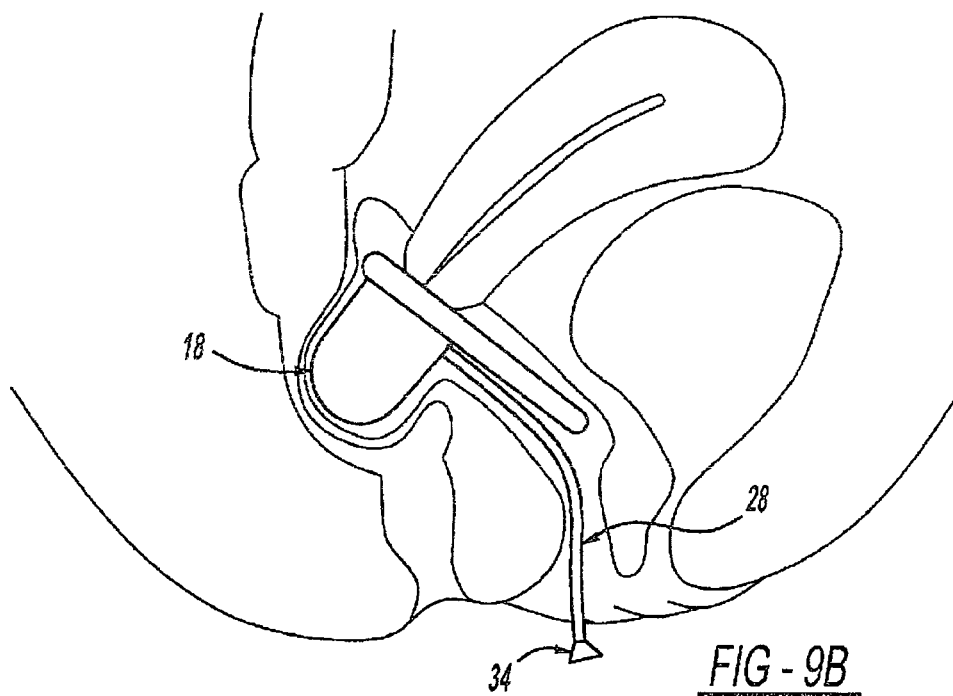
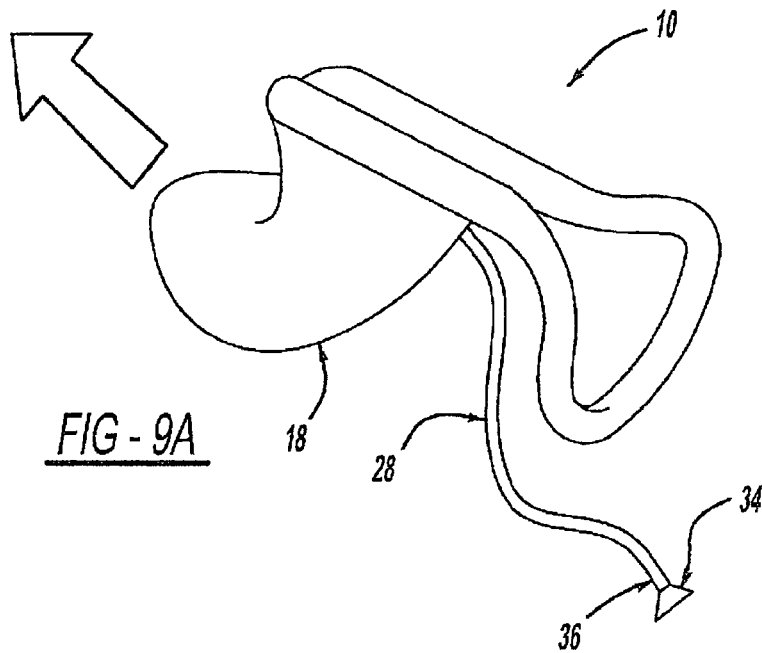




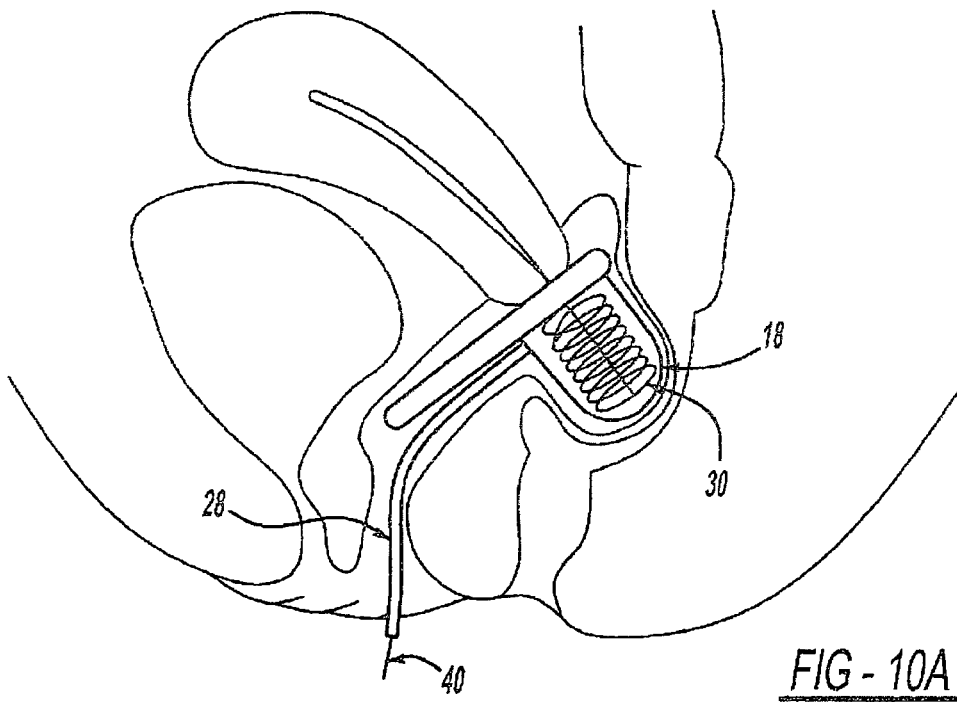
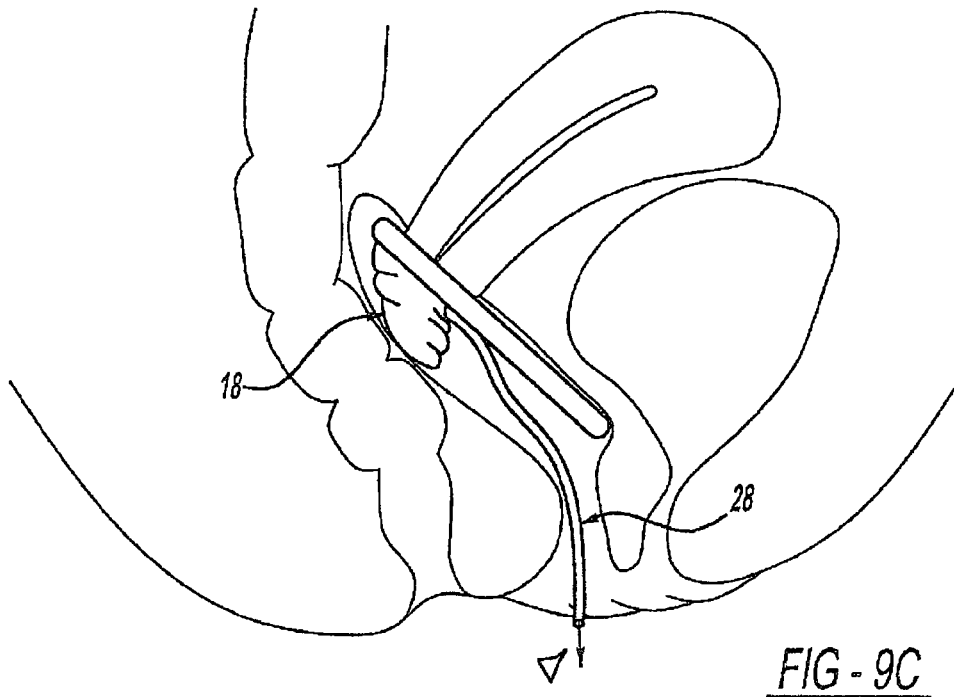


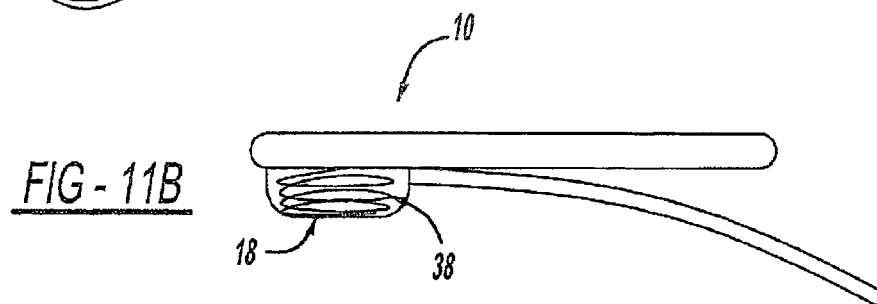
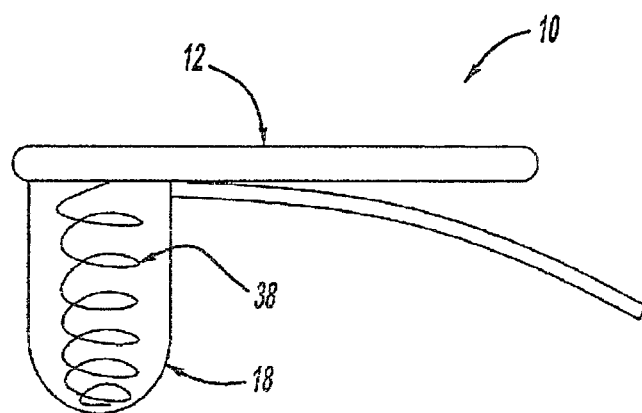
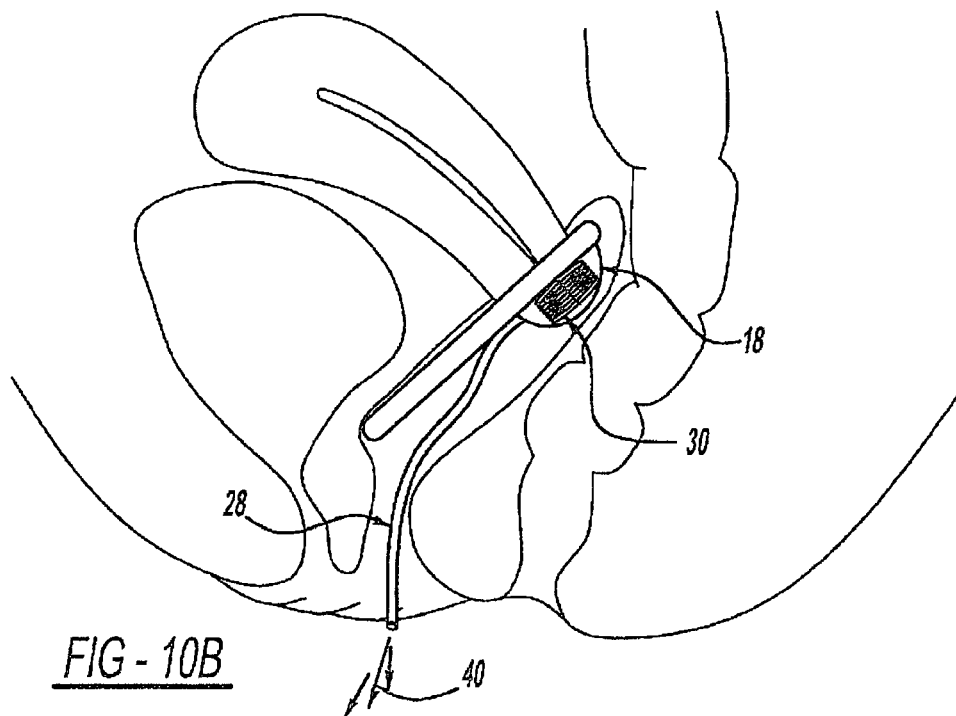












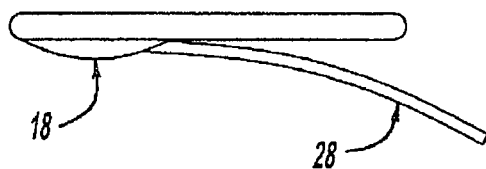


FIG - 11C

FIG - 11D

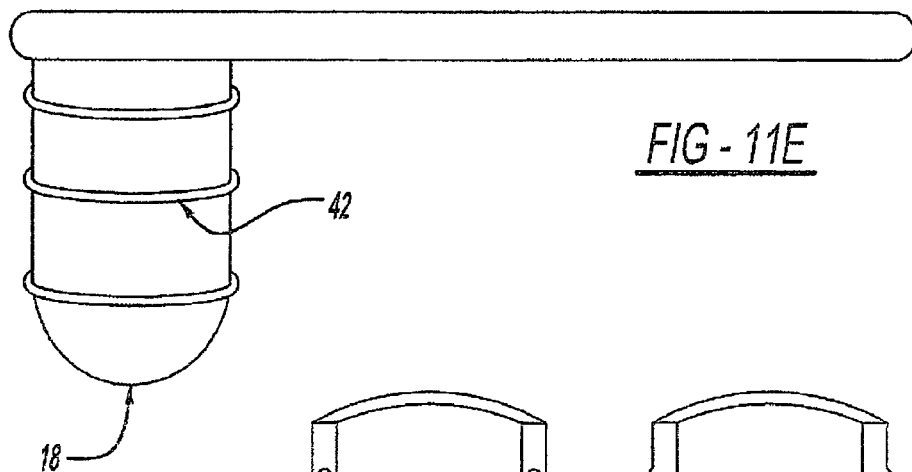
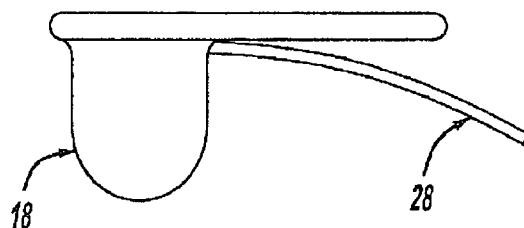


FIG - 11E

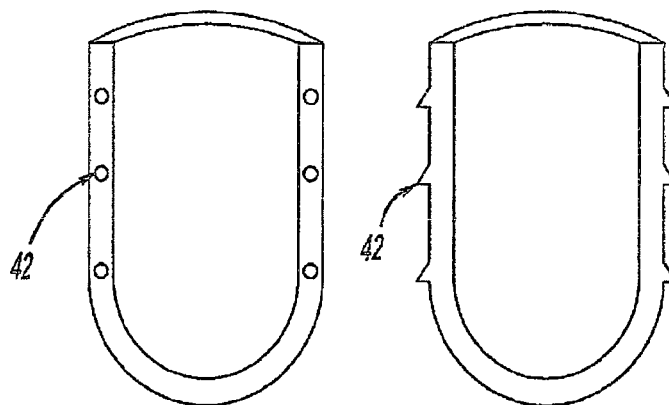


FIG - 11F

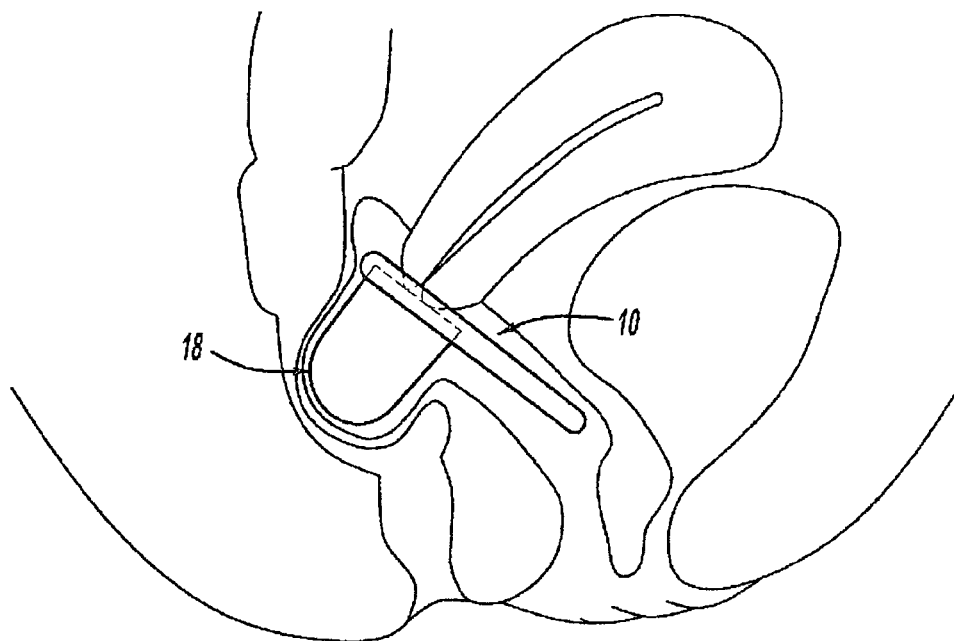


FIG - 12A

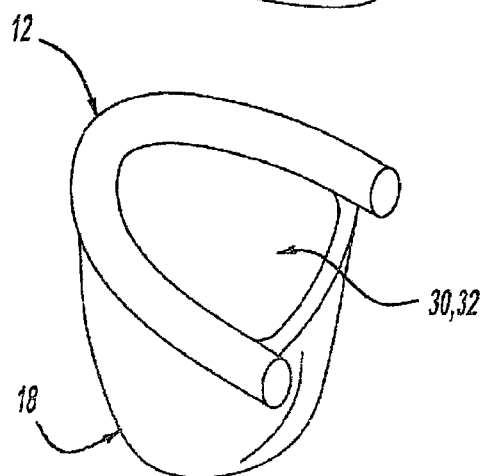


FIG - 12B

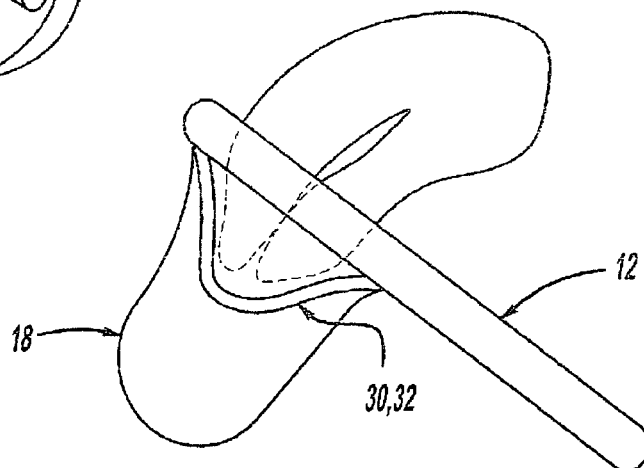


FIG - 12C

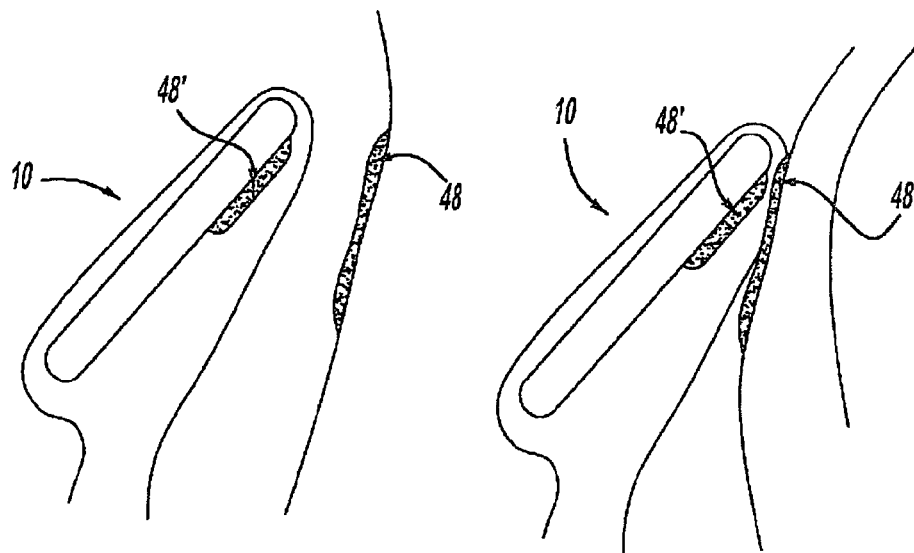


FIG - 13A

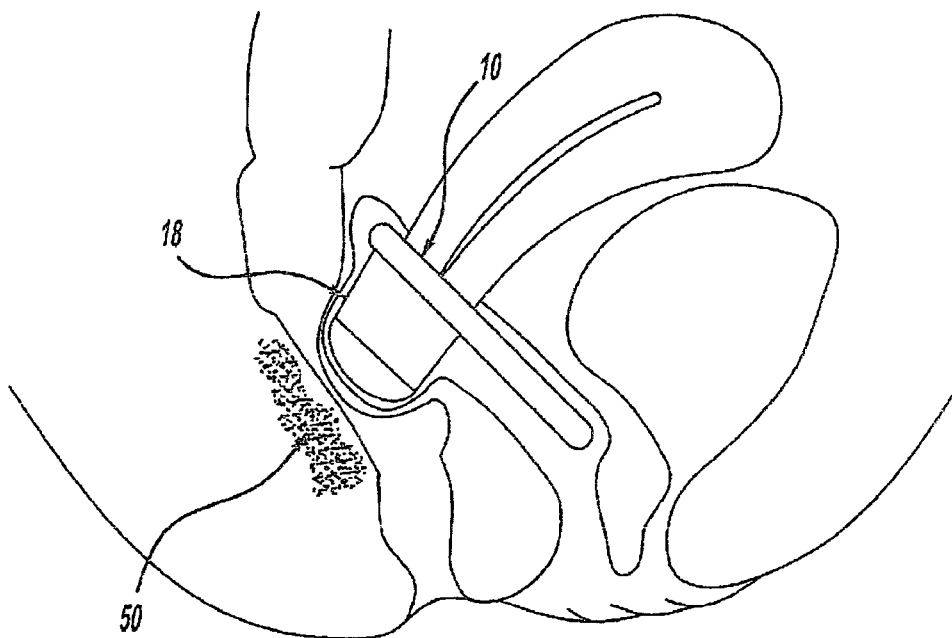
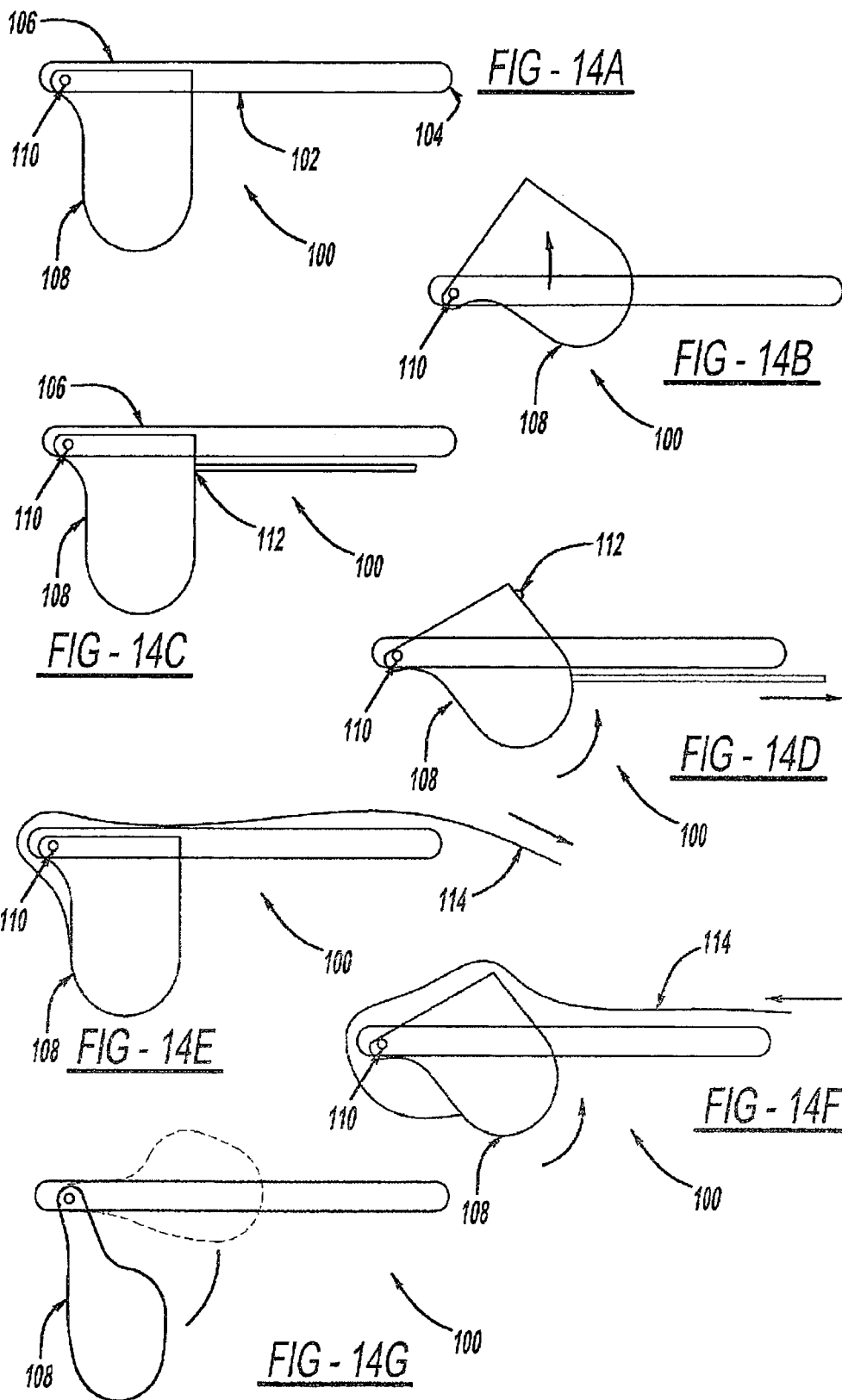
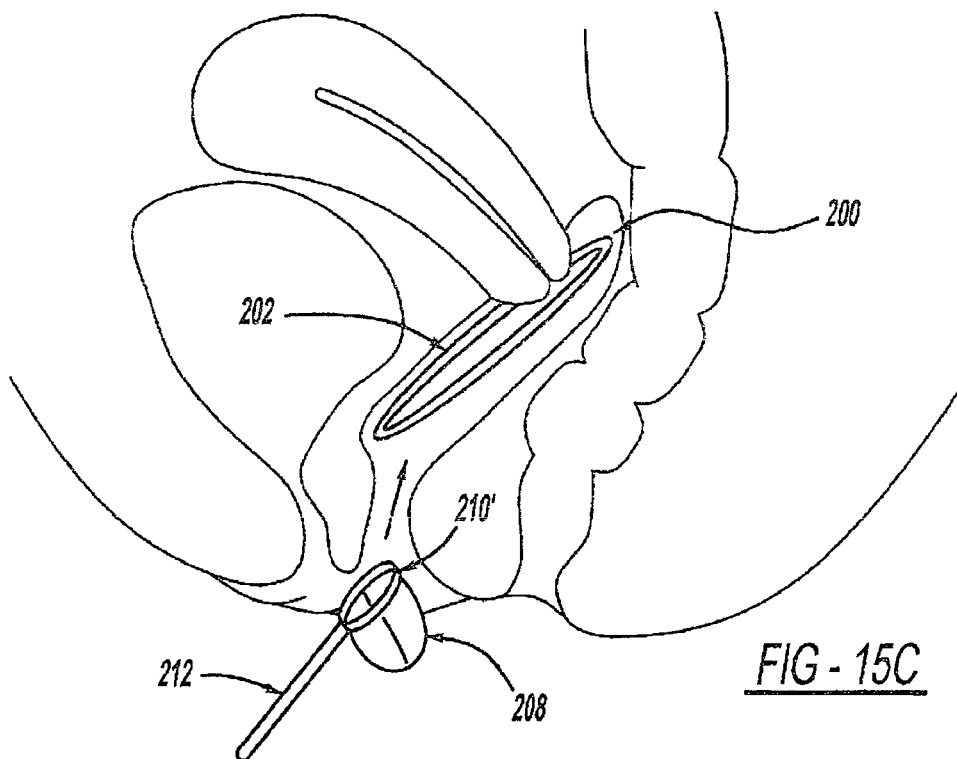
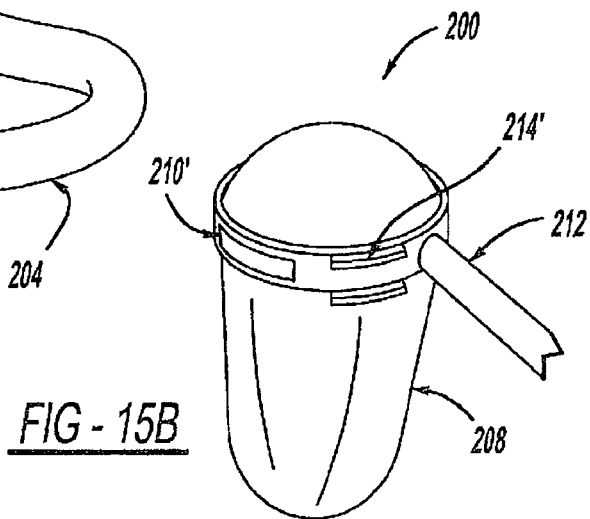
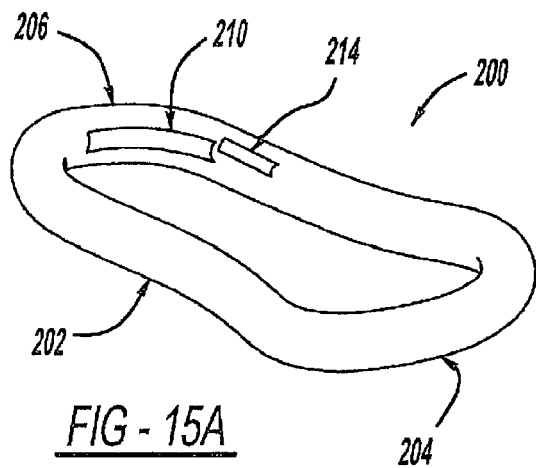
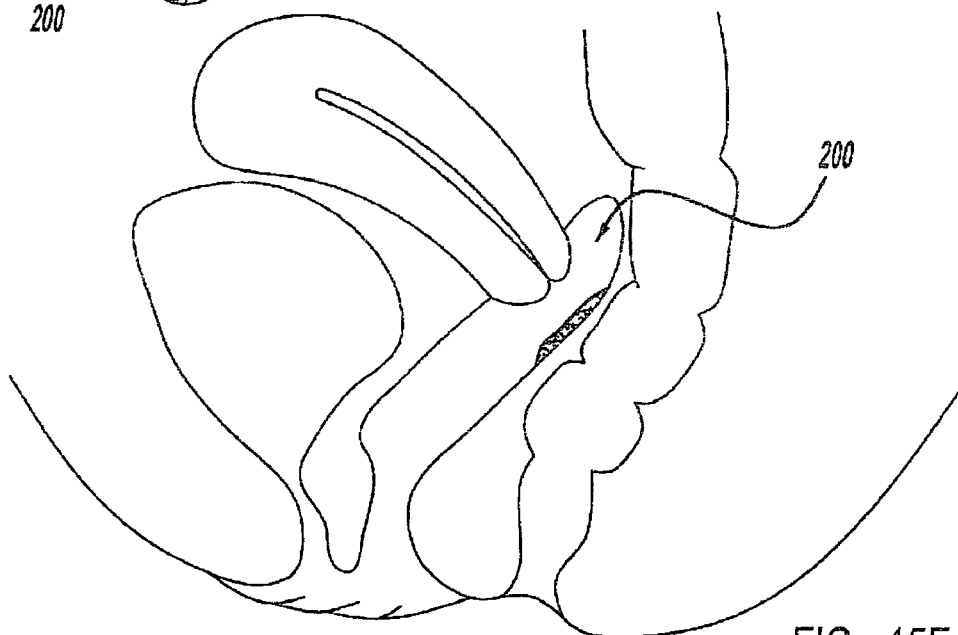
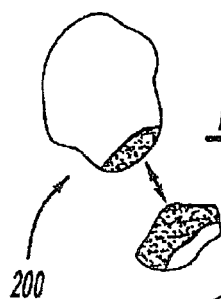
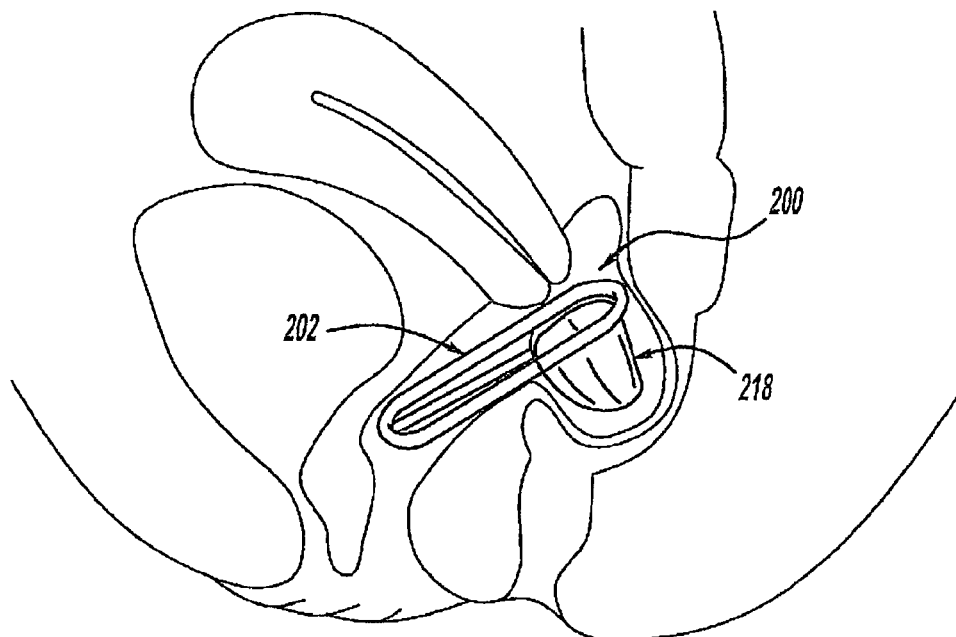


FIG - 13B









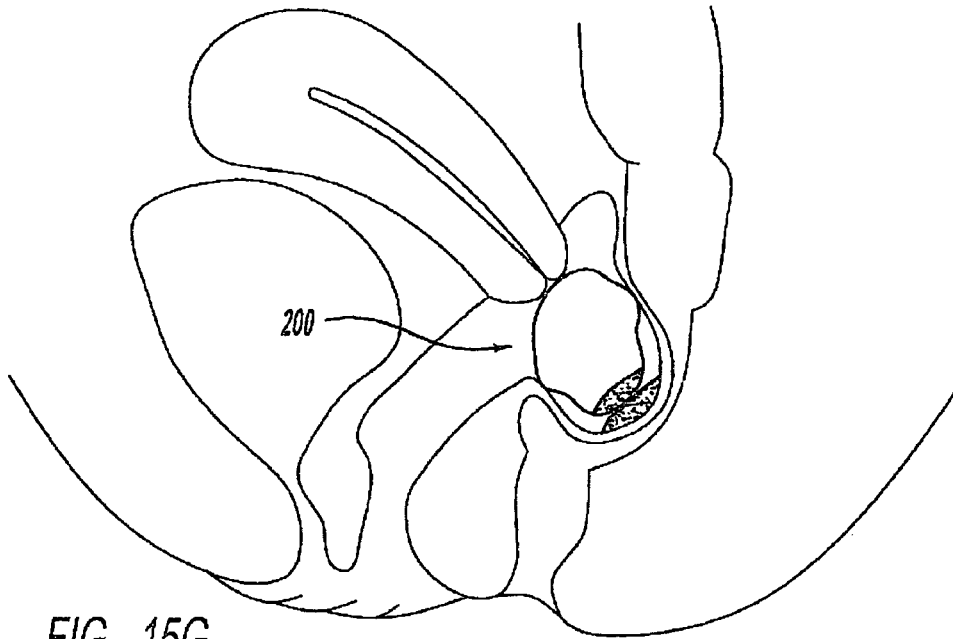


FIG - 15G

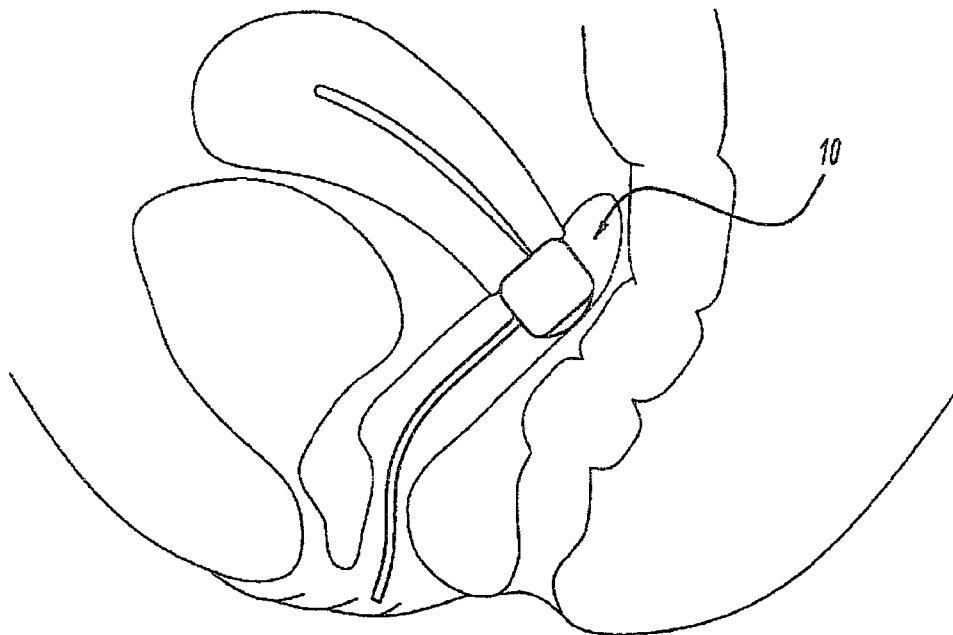


FIG - 16A

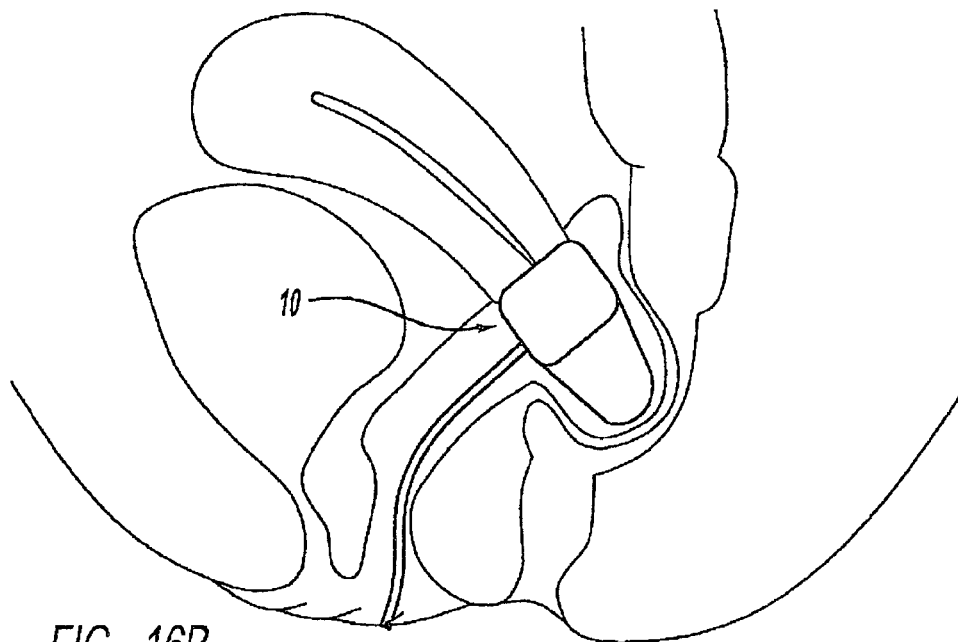


FIG - 16B

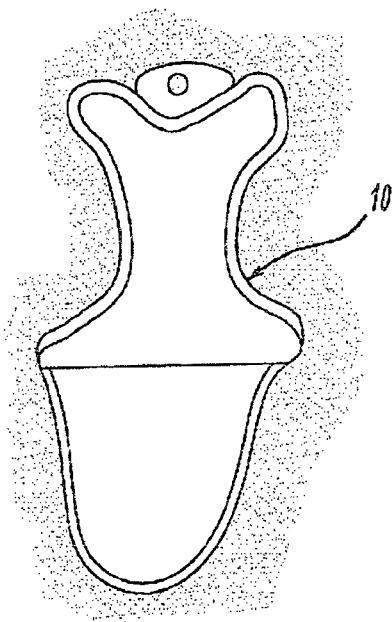


FIG - 16C

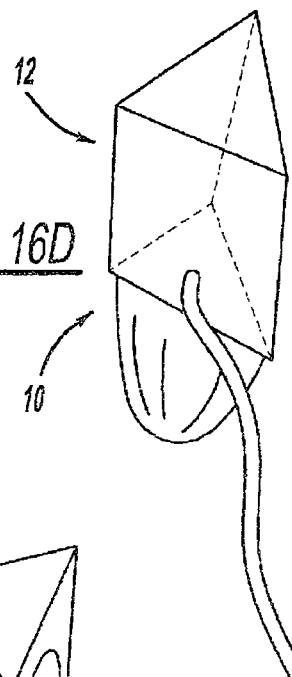


FIG - 16D

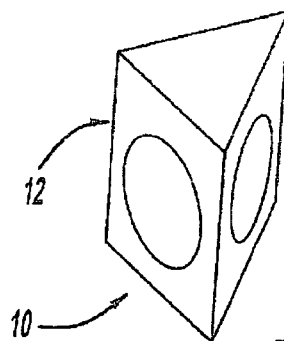


FIG - 16E

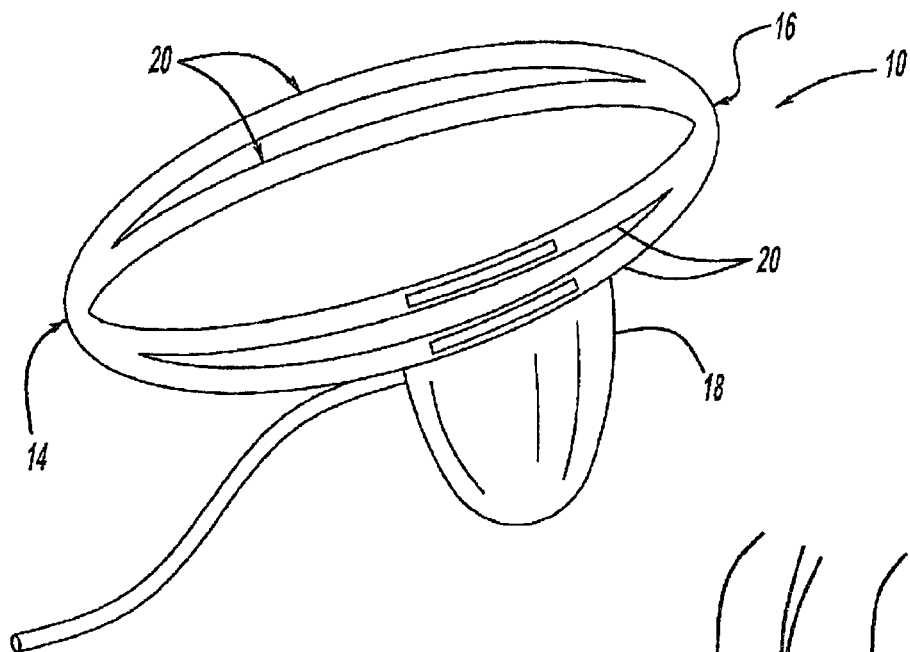


FIG - 17A

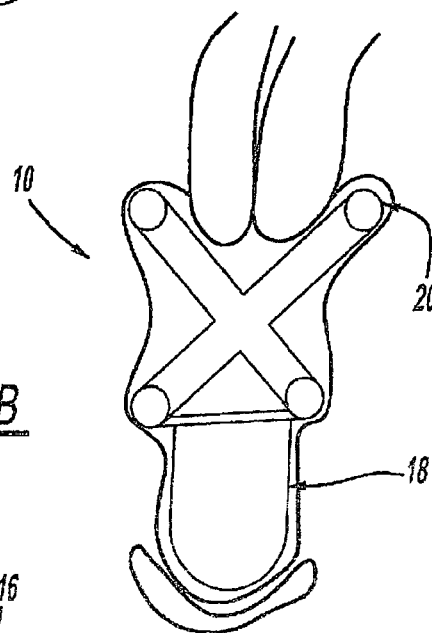


FIG - 17B

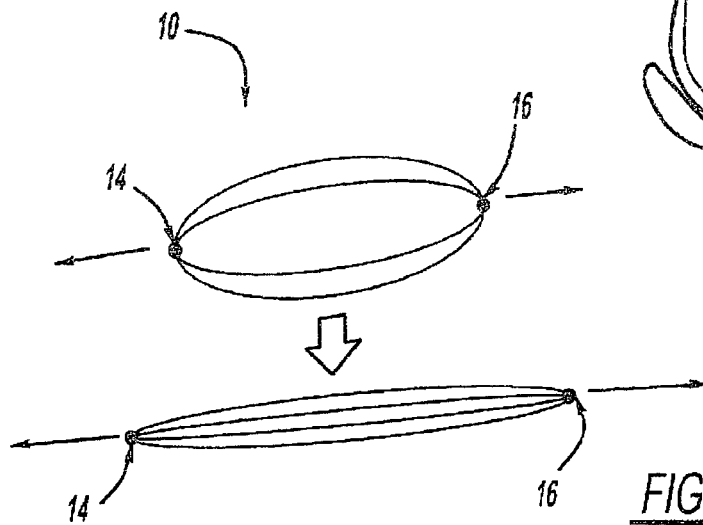
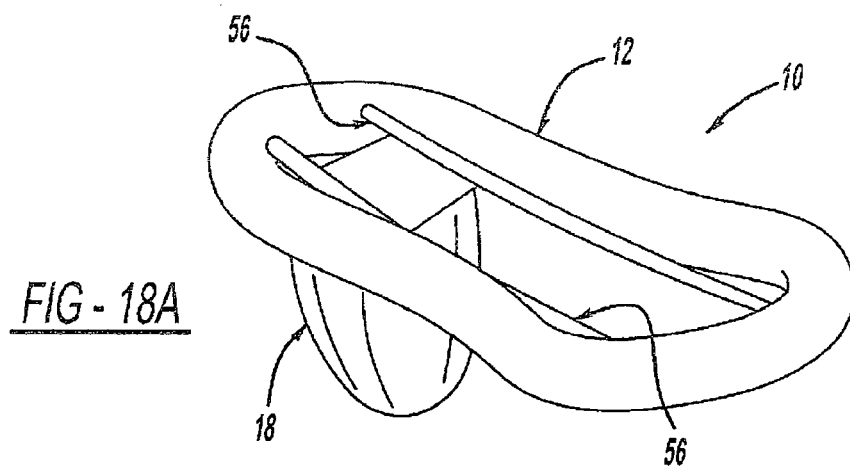
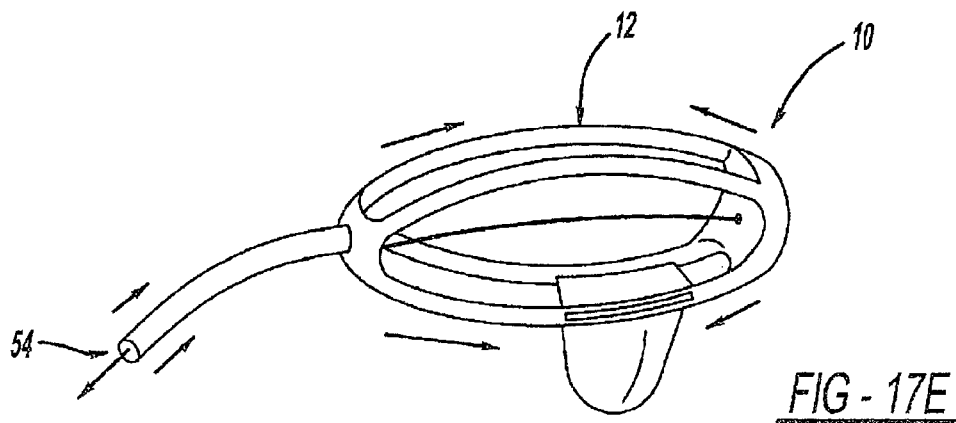
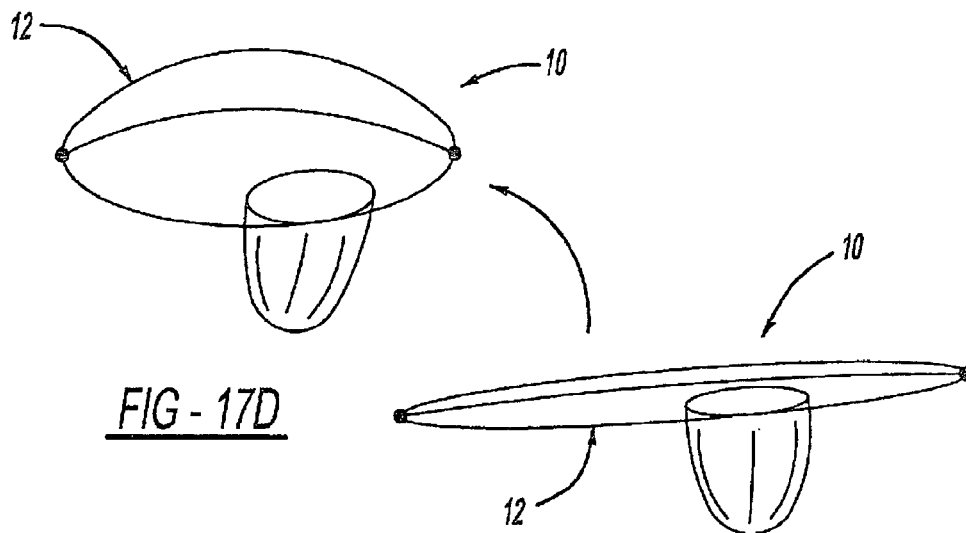
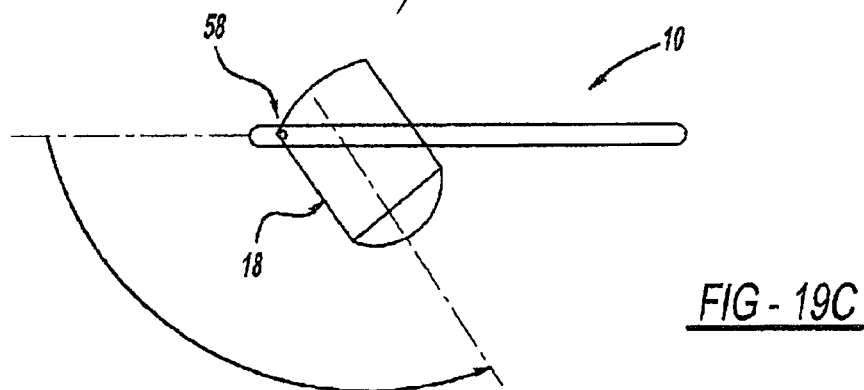
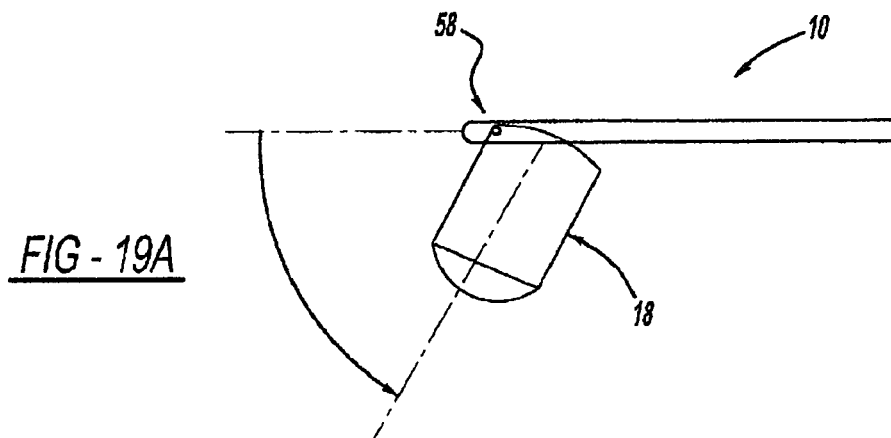
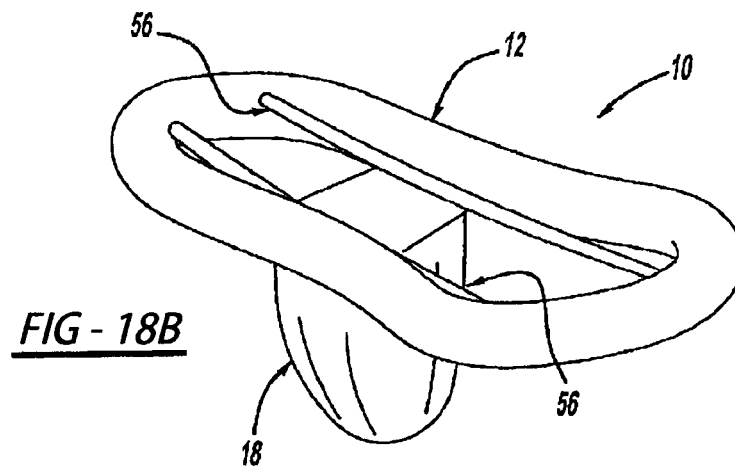


FIG - 17C





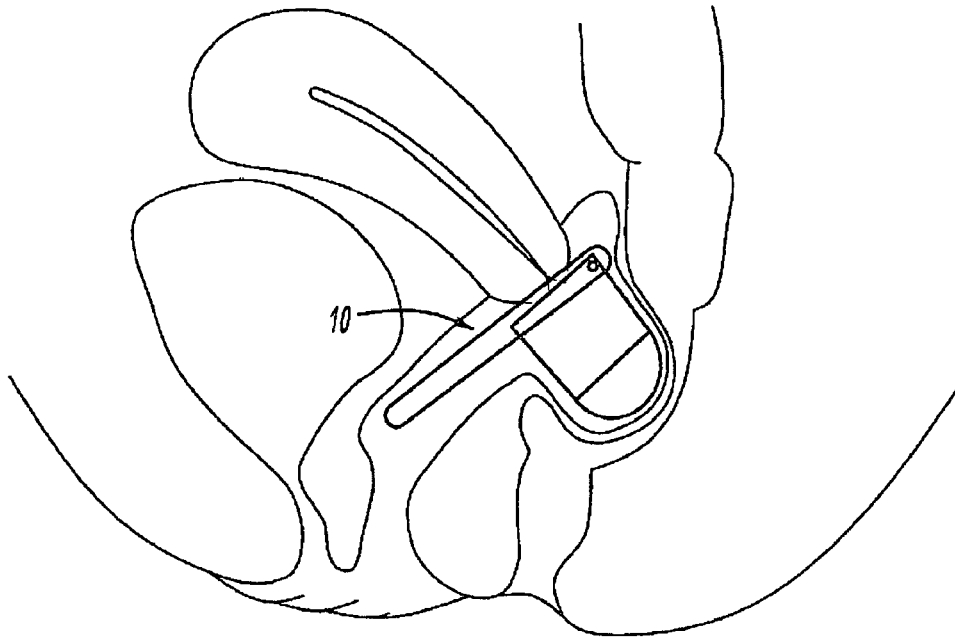


FIG - 19B

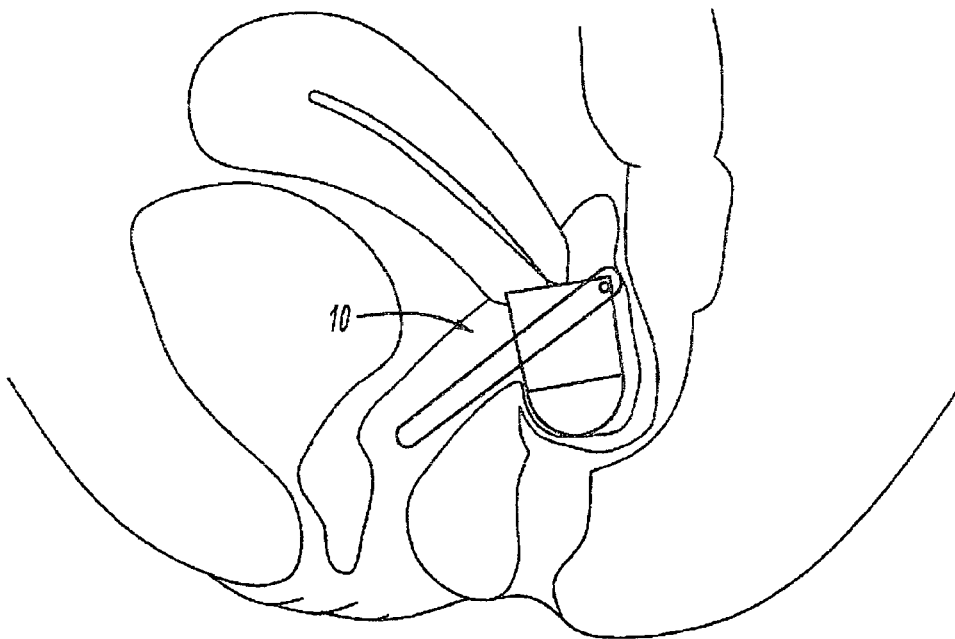


FIG - 19D

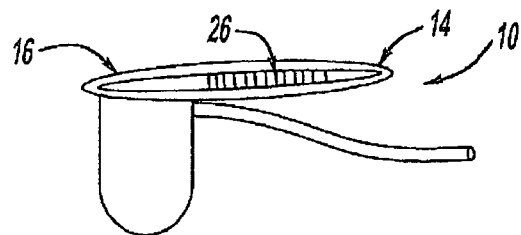


FIG - 20A

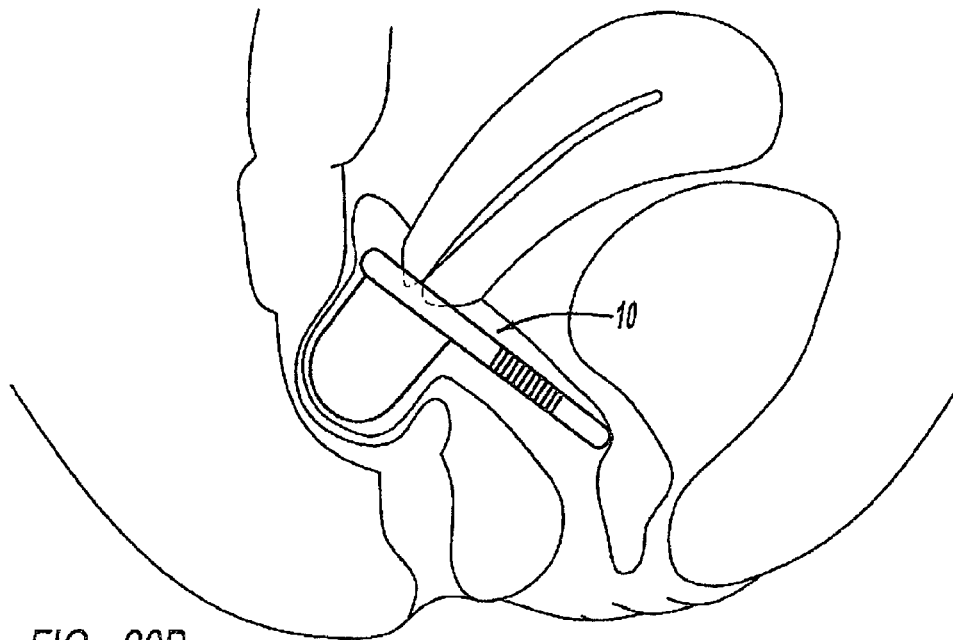


FIG - 20B

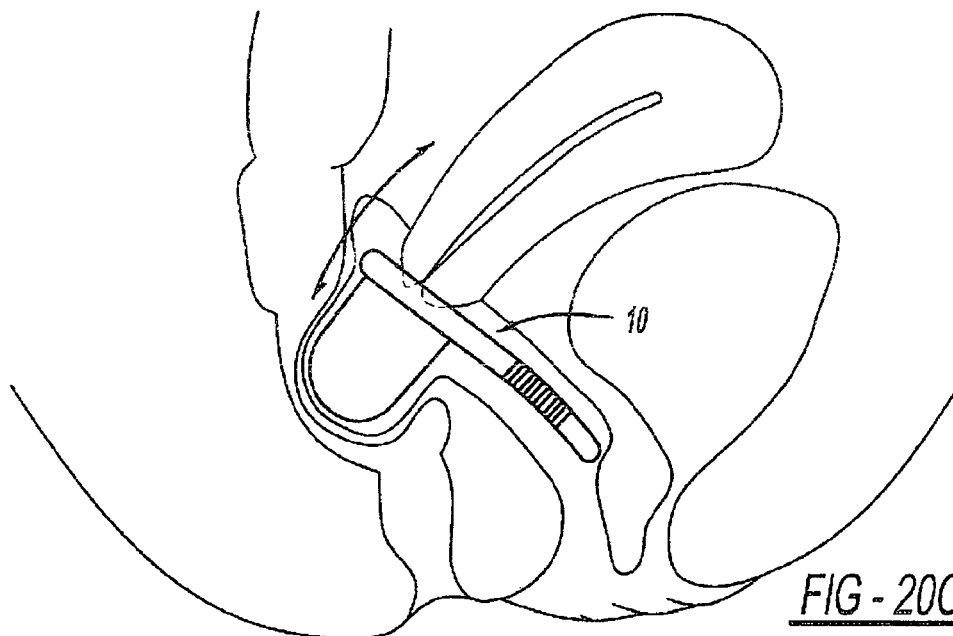


FIG - 20C

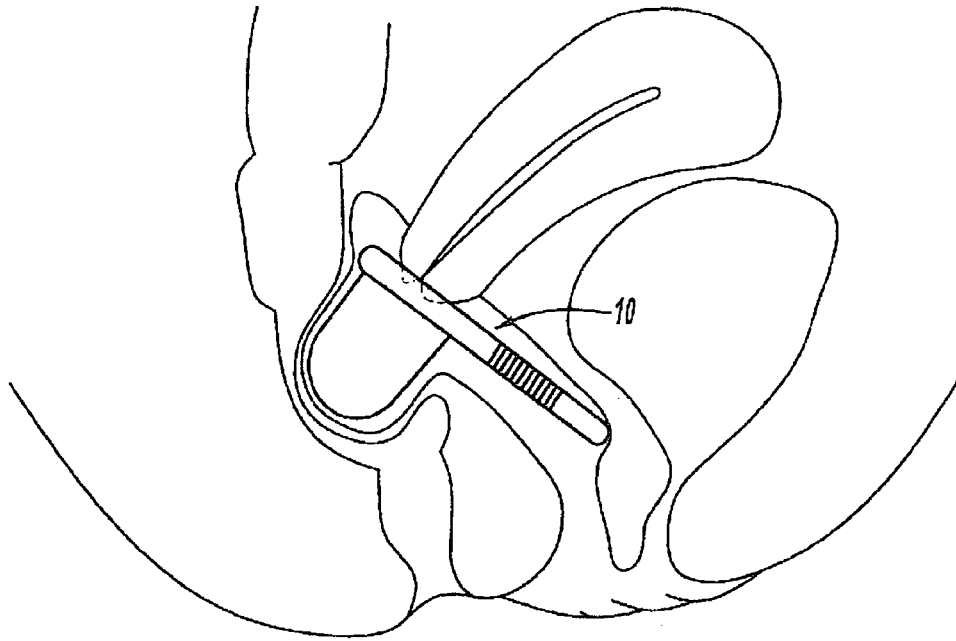


FIG - 20D

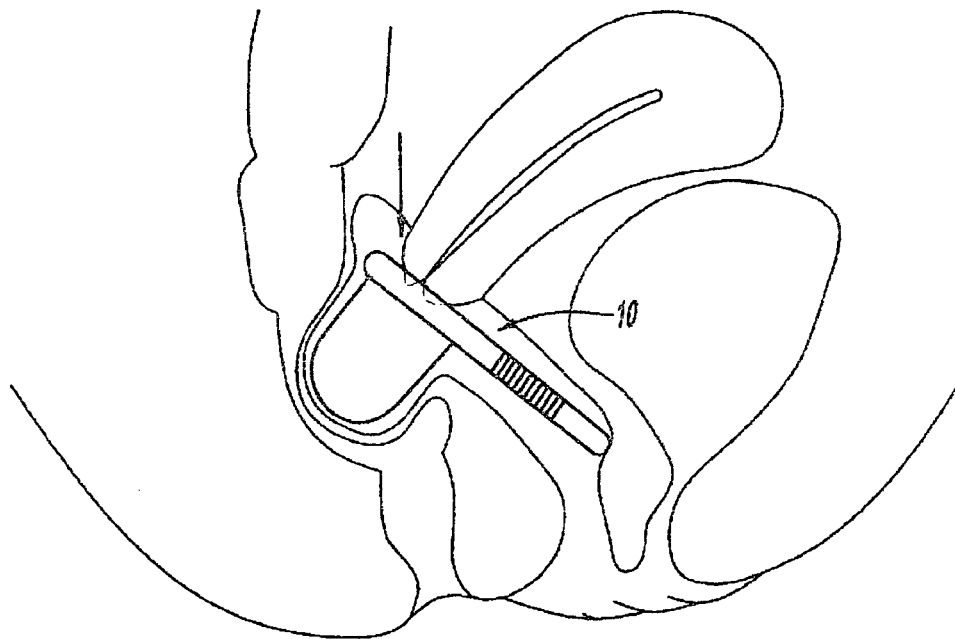


FIG - 20E



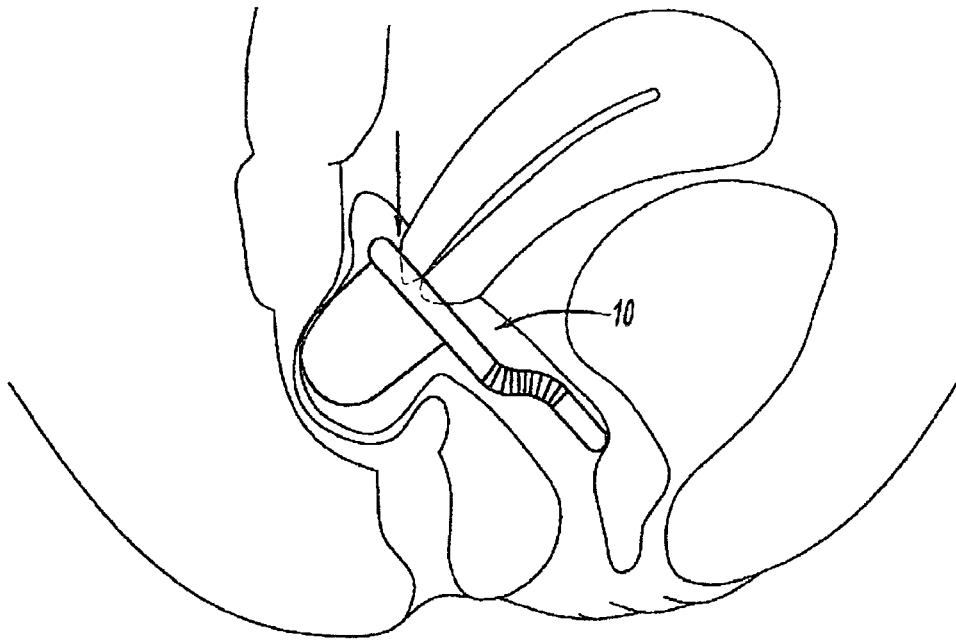


FIG - 20F

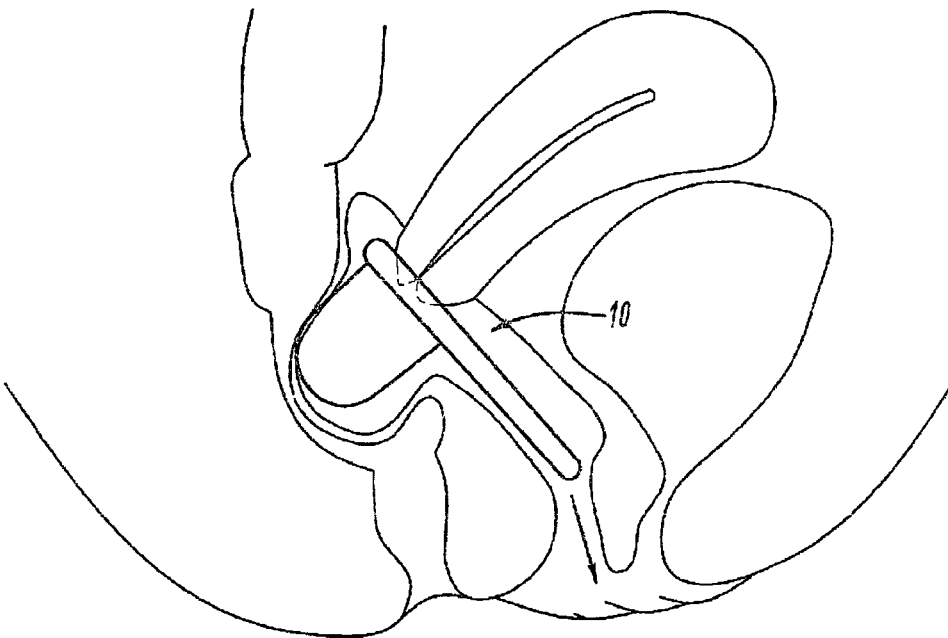


FIG - 20G

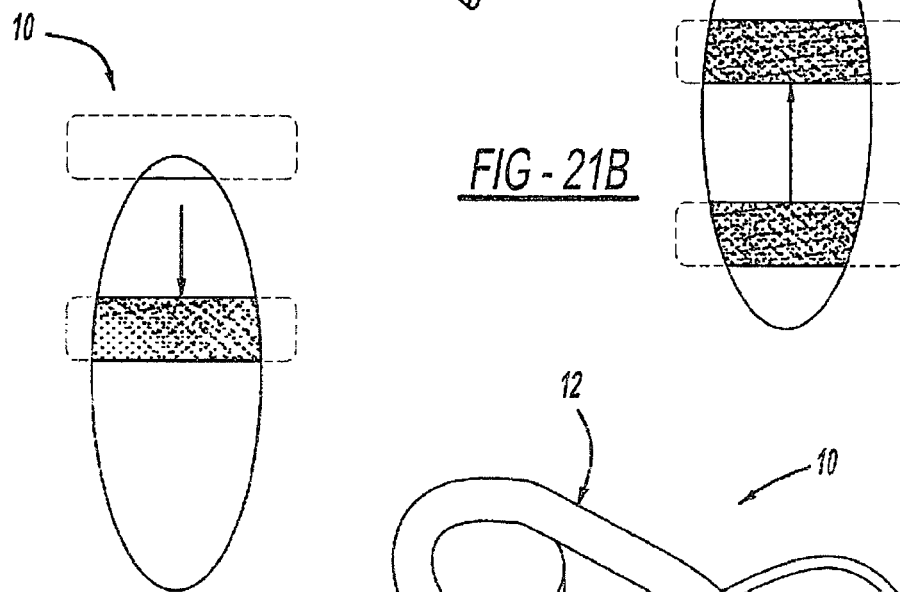
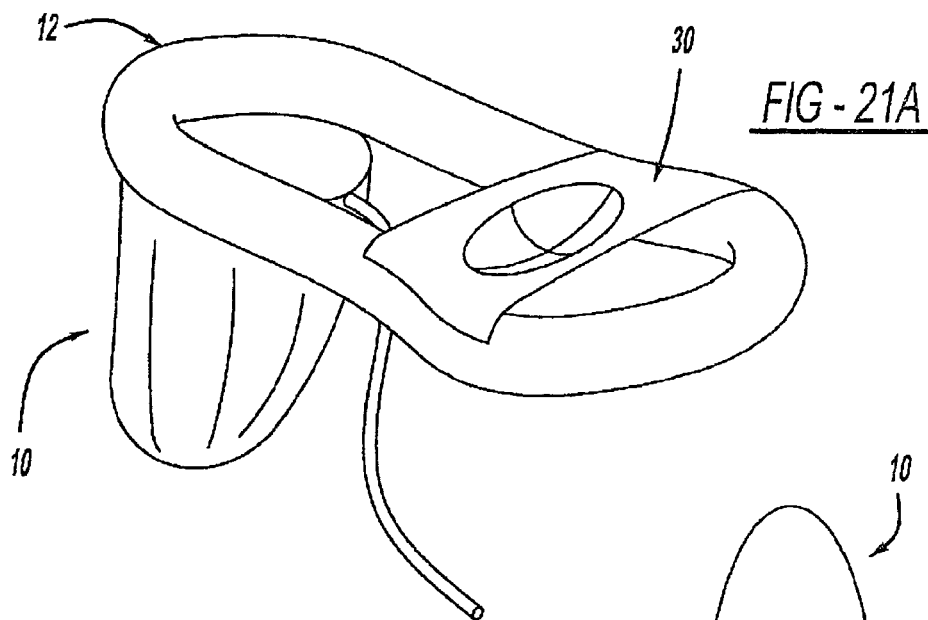
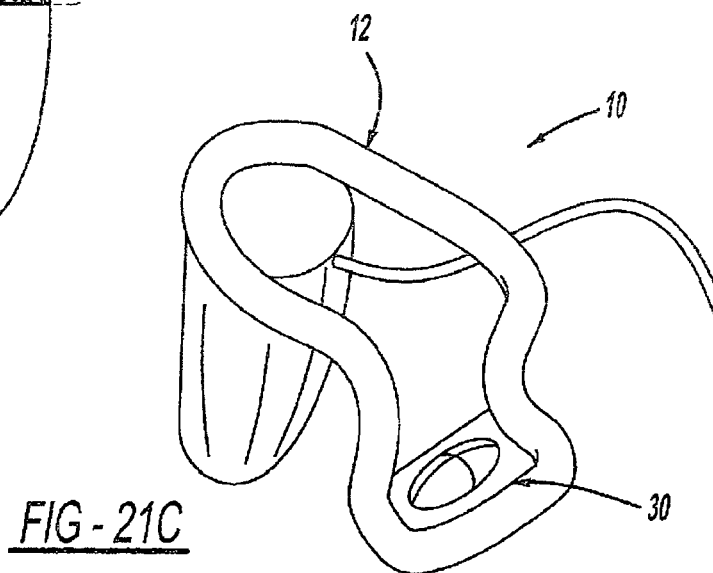


FIG - 21D



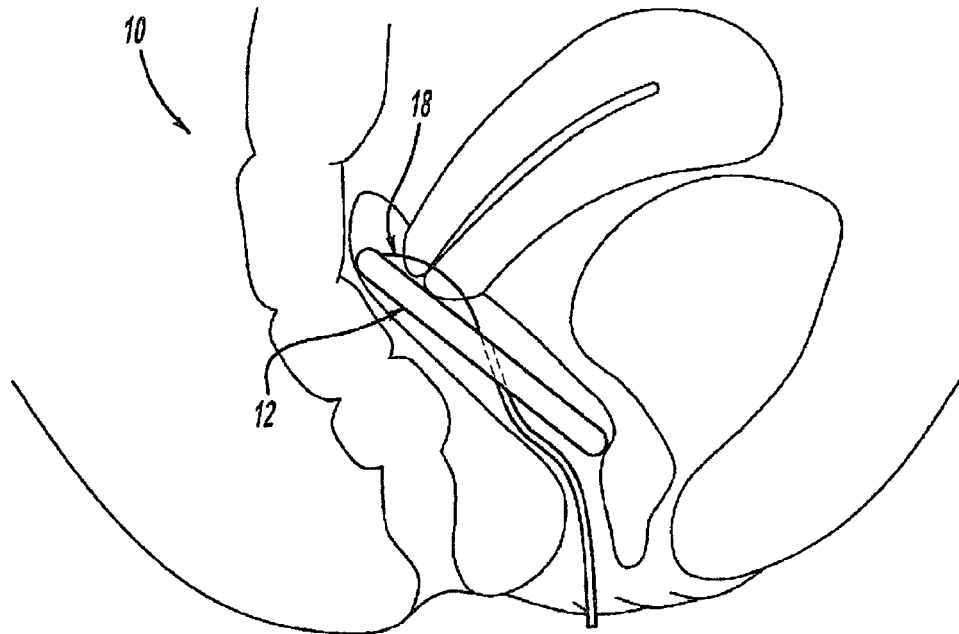


FIG - 22A

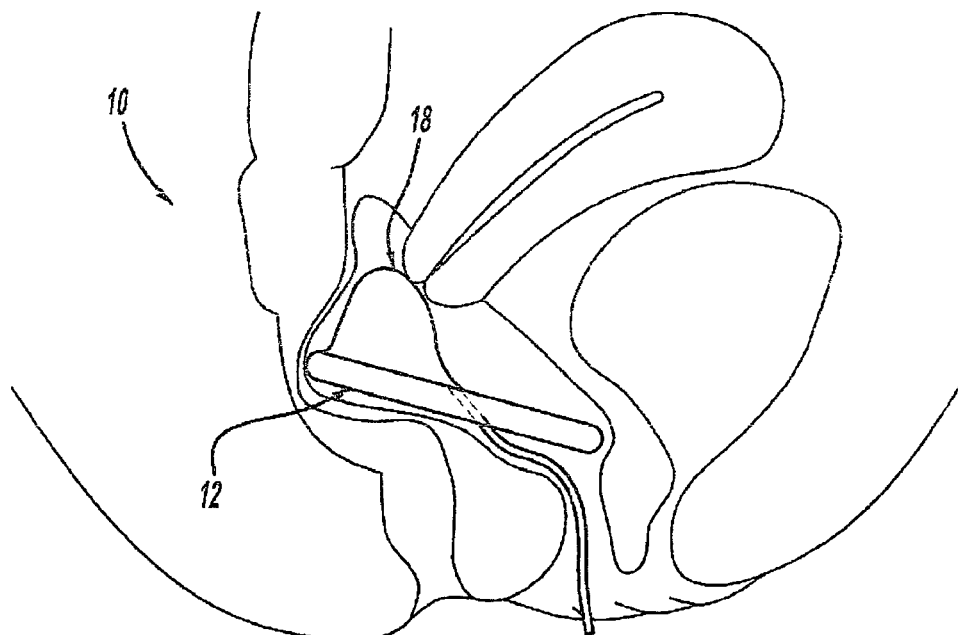
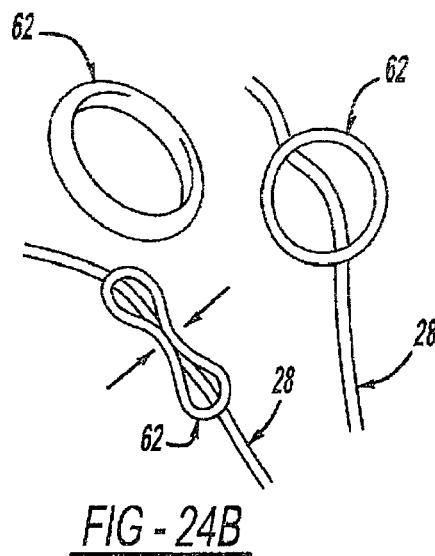
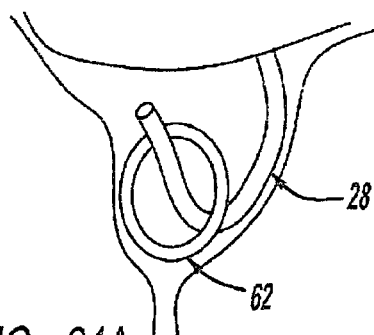
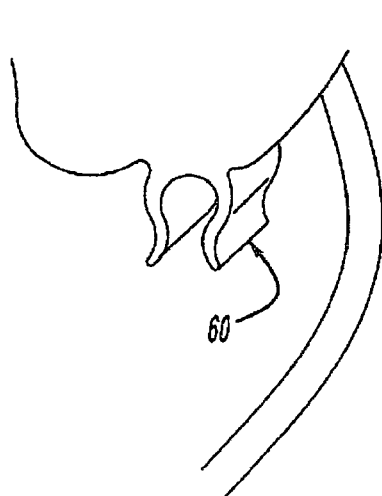
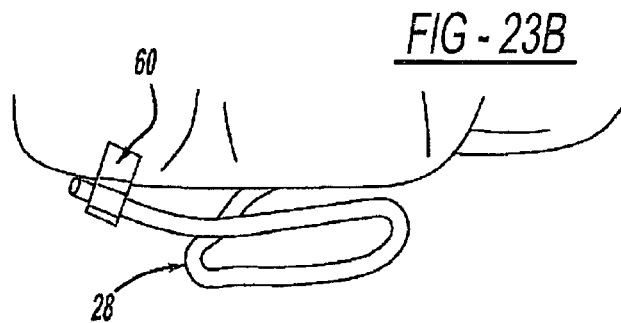
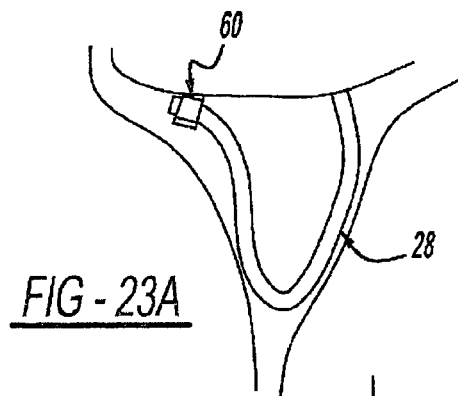


FIG - 22B



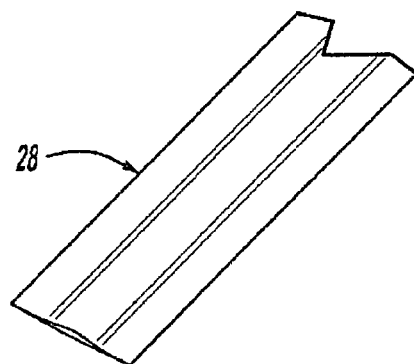


FIG - 25A

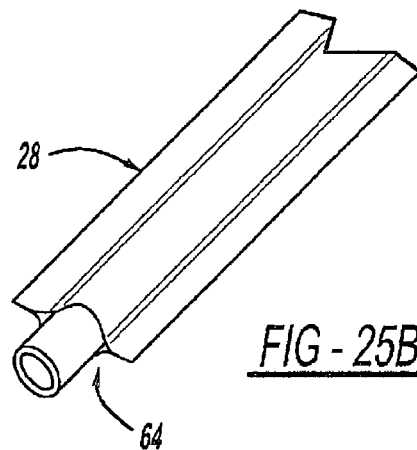


FIG - 25B

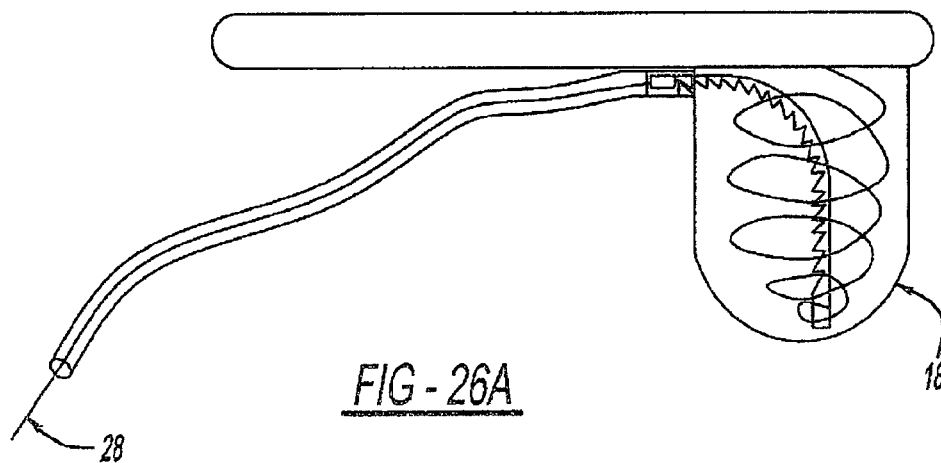


FIG - 26A

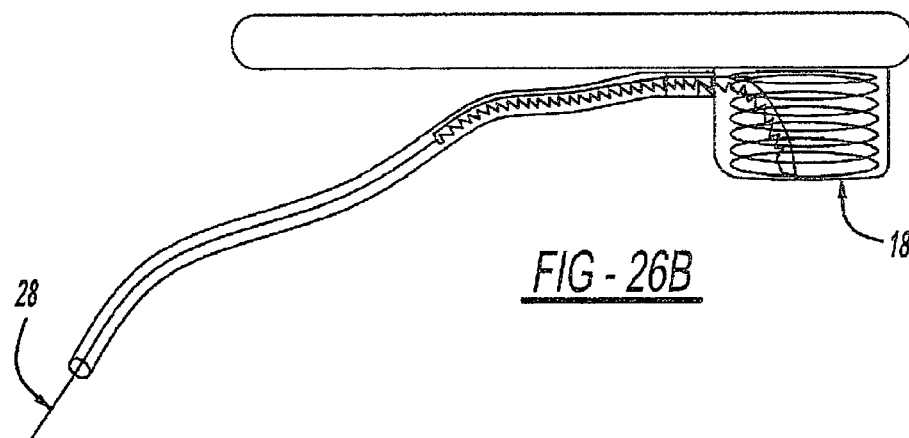


FIG - 26B

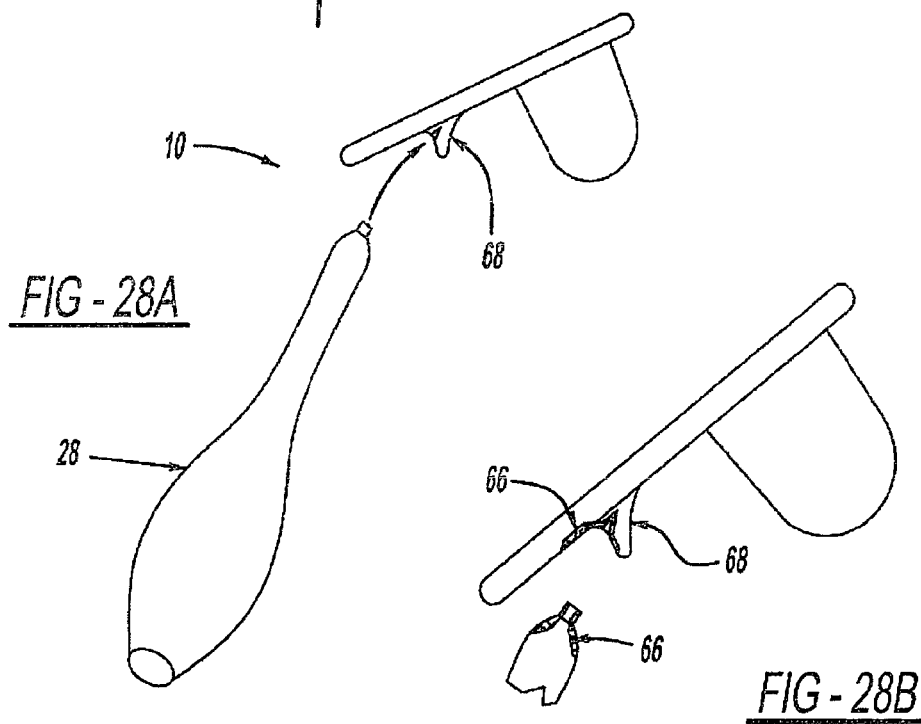
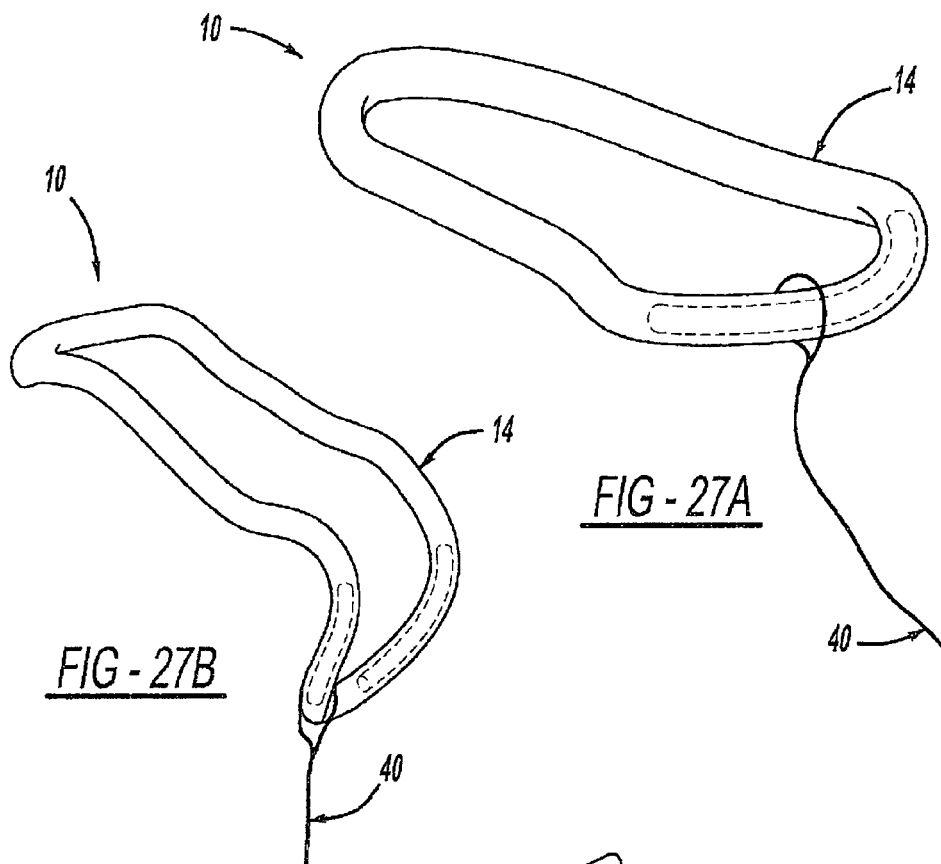


FIG - 28C

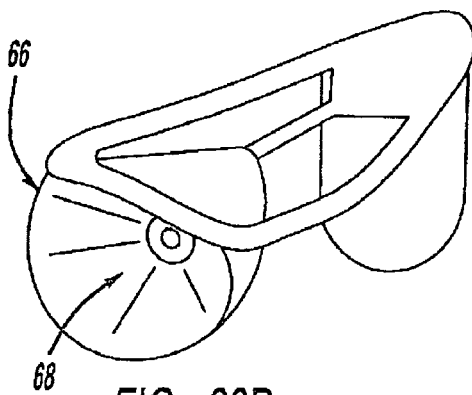
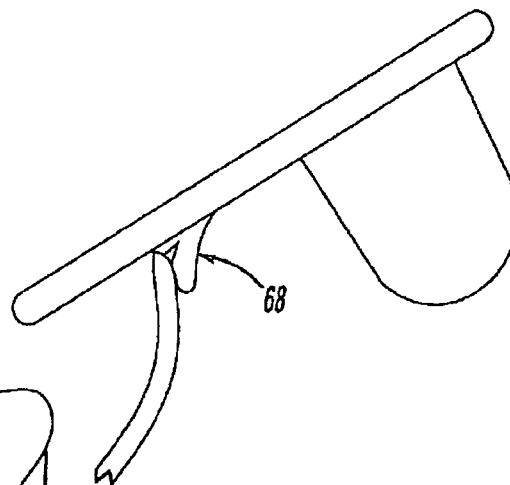


FIG - 28D

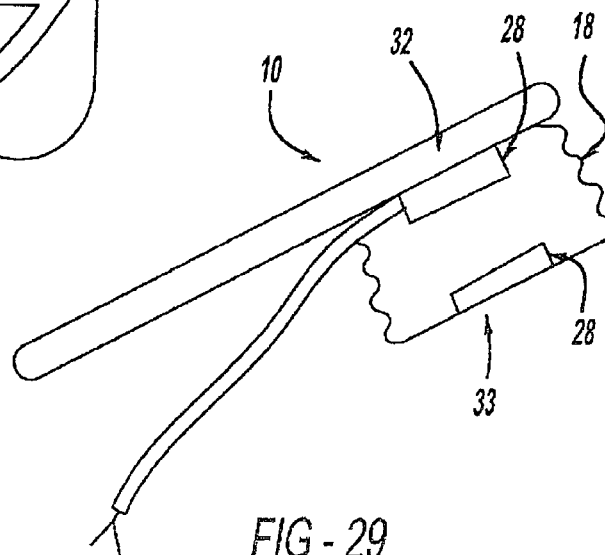


FIG - 29

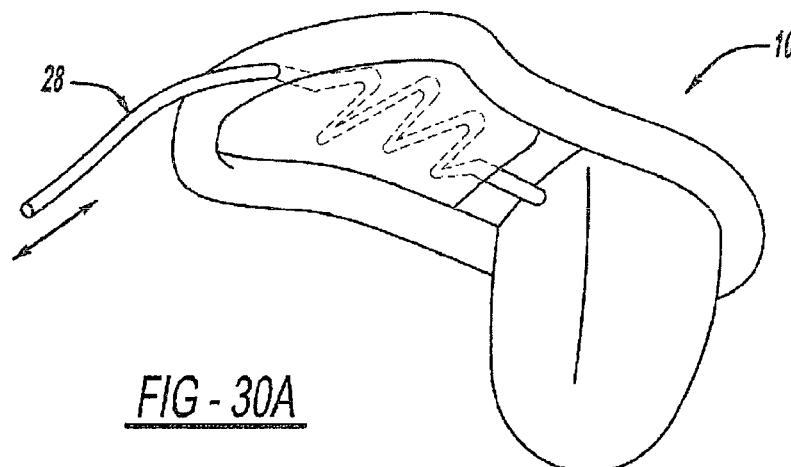
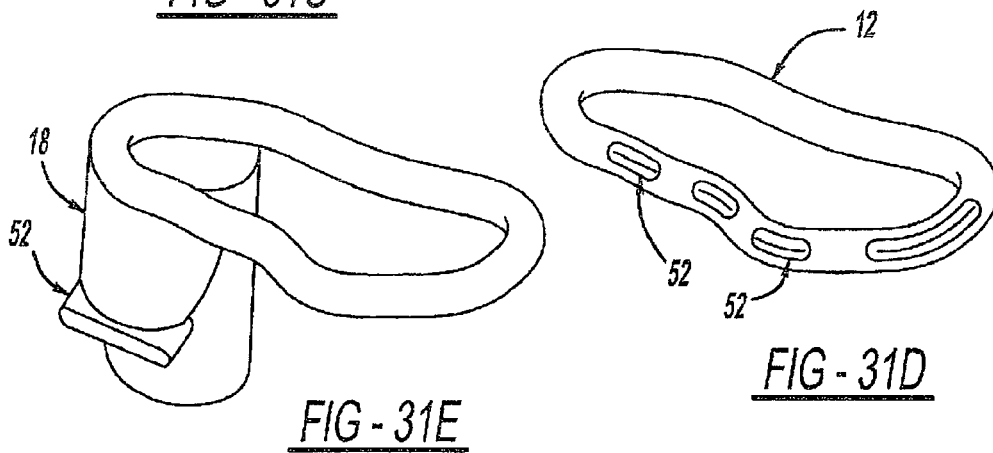
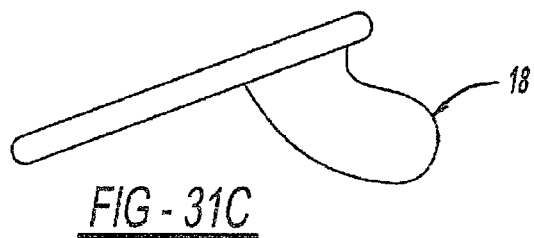
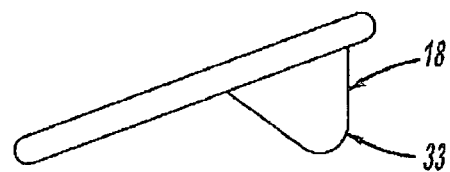
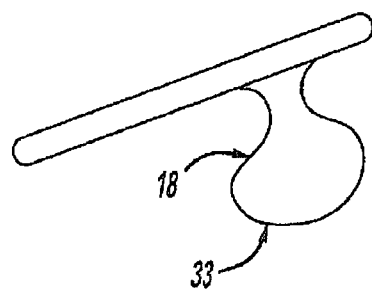
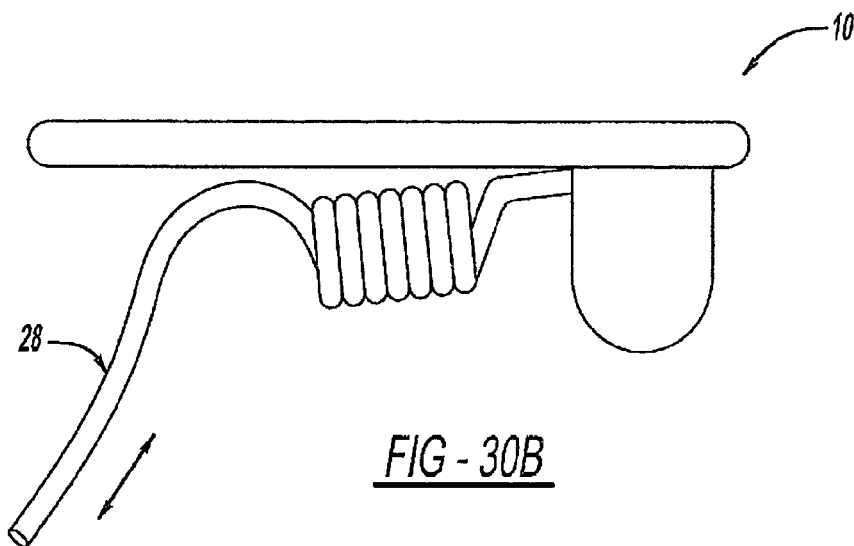


FIG - 30A





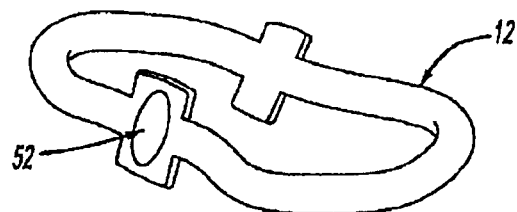


FIG - 31F

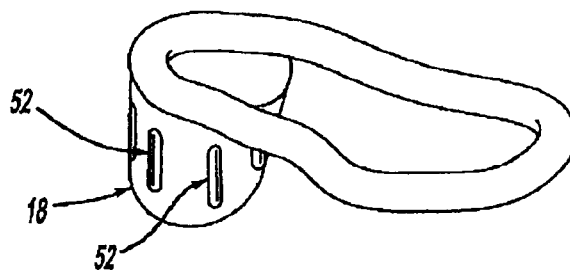


FIG - 31G

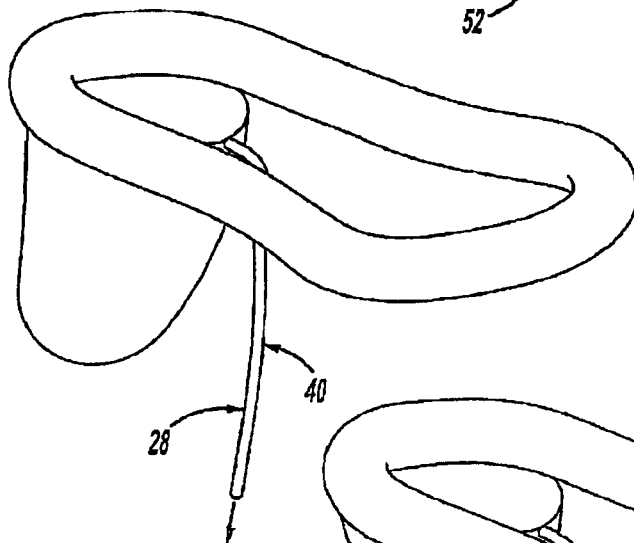


FIG - 32A

FIG - 32B

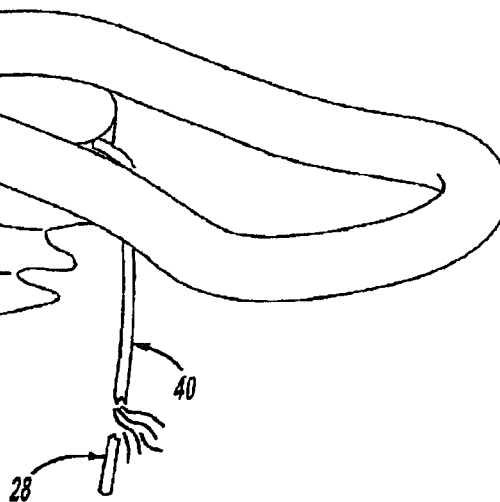


FIG - 33A

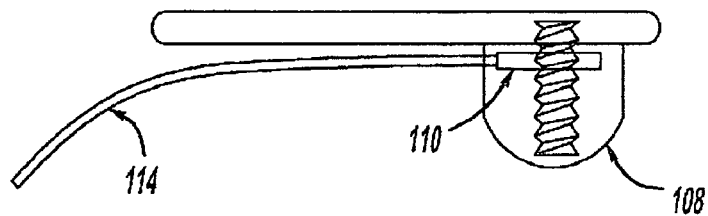


FIG - 33B

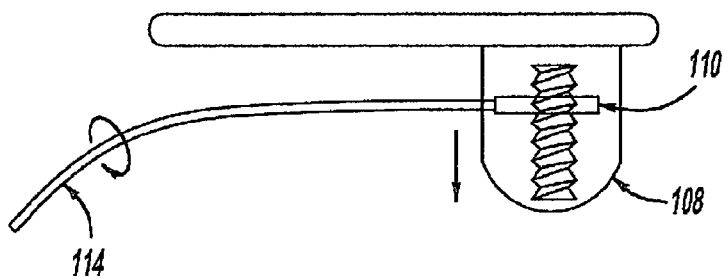


FIG - 33C

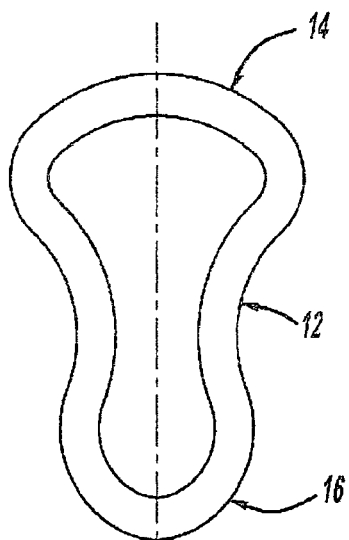
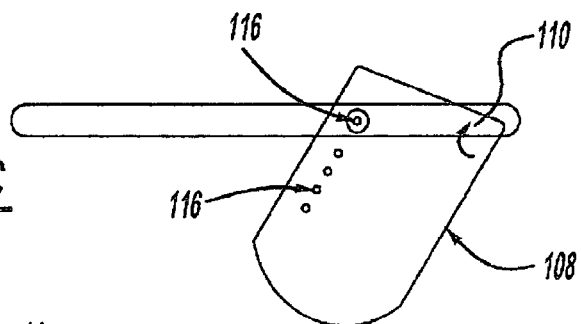


FIG - 34A

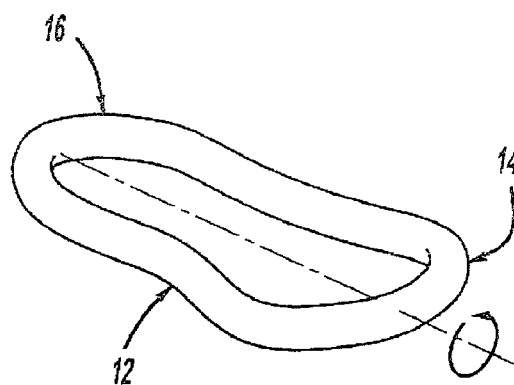


FIG - 34B

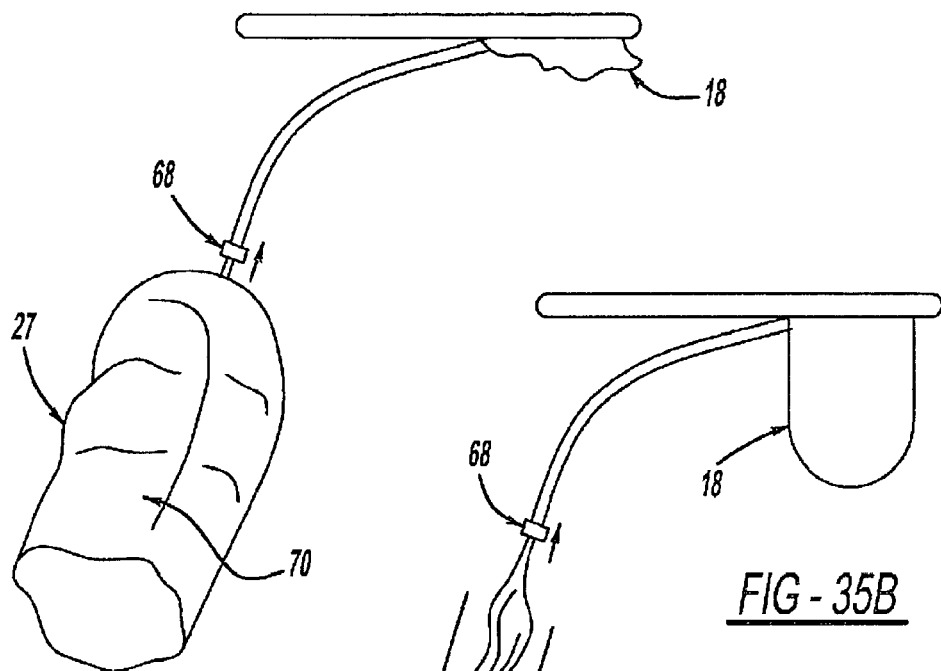


FIG - 35A

FIG - 35B

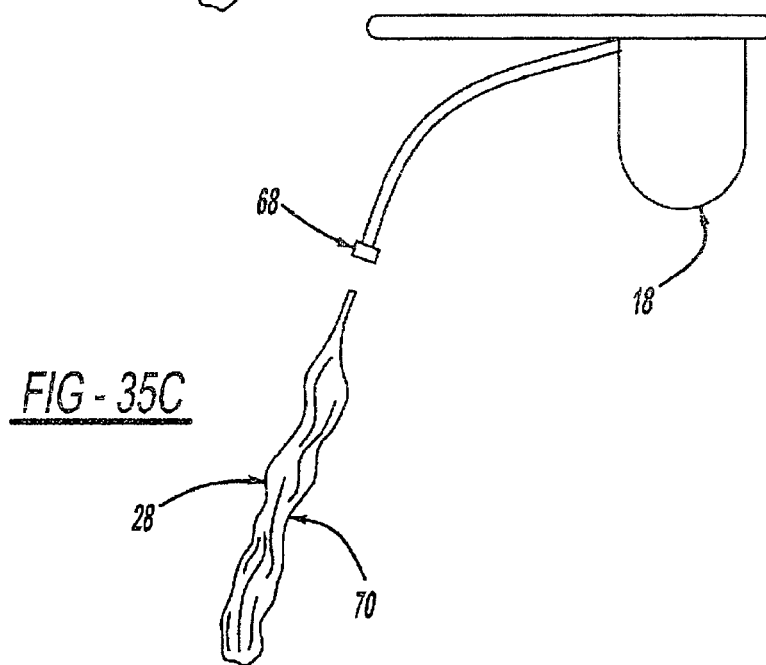
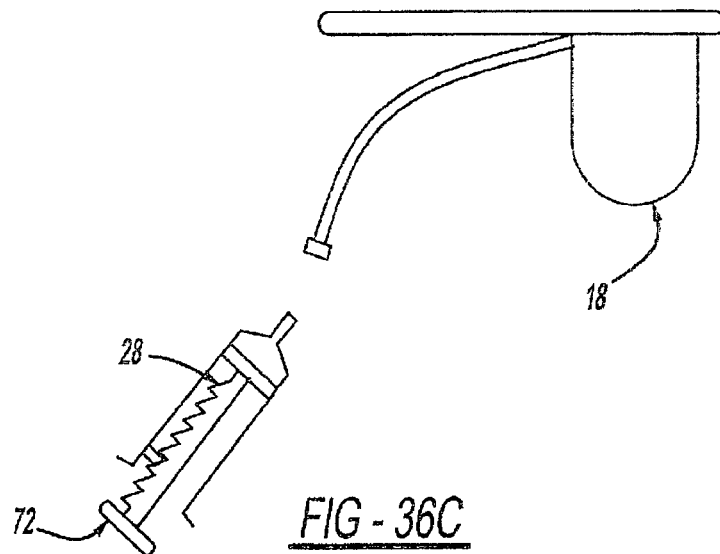
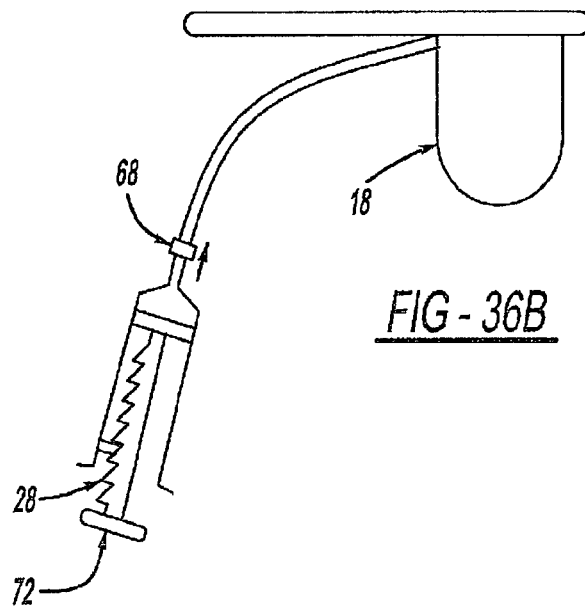
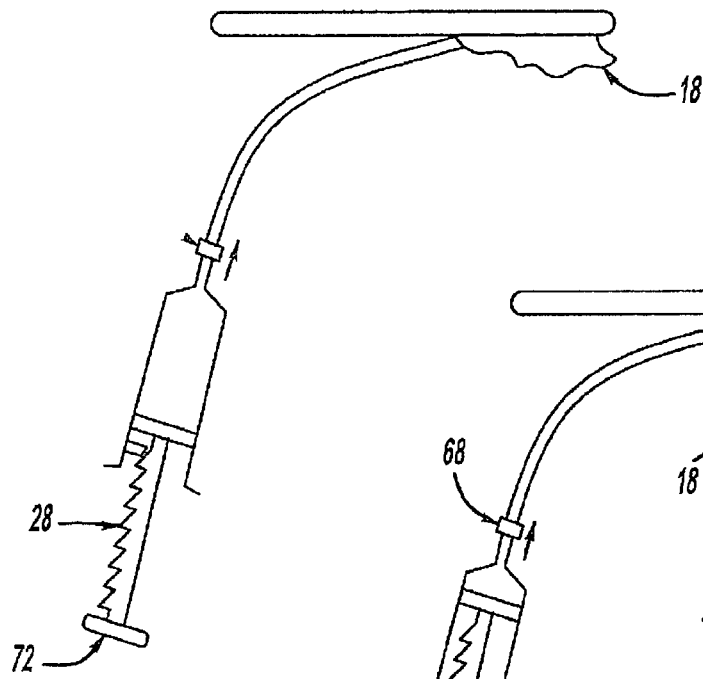


FIG - 35C



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# INTRA-VAGINAL DEVICE FOR FECAL INCONTINENCE

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is the U.S. National Phase of International Application Ser. No. PCT/US2011/028691, filed on Mar. 16, 2011, which claims the benefit of U.S. Provisional Application Ser. No. 61/367,418, filed on Jul. 25, 2010 and U.S. Provisional Application Ser. No. 61/314,335, filed on Mar. 16, 2010.

## TECHNICAL FIELD

The present invention relates to intra-vaginal devices. More specifically, the present invention relates to intra-vaginal devices for the control of stool passage.

## BACKGROUND OF THE INVENTION

Fecal incontinence (FI), or the inability to control bowel movements, is an immense unmet clinical need, especially among women, who are 9 times more likely to suffer from the disease than men. While stigma surrounding the disease has masked the prevalence of the condition for decades, recent community-based studies estimate that up to 17 million women suffer from FI in the U.S. alone. The disease is psychologically and emotionally devastating, causing those afflicted to avoid going out in public and greatly reducing their quality of life. With no good treatments, most patients are left to cope with the disease wearing diapers.

Prevalence rates are higher in women because of the trauma caused to the pelvic floor during pregnancy and child delivery. Contributing pathophysiologies include damage to the external or internal anal sphincters, the pudendal nerve, the levator ani, and other muscles in the pelvic floor. This damage can immediately result in symptoms, or symptoms can not manifest until later in life. The latter is due to the fact that as this population ages, they experience age-related decreases in general continence mechanisms, such as changes in rectal sensation, compliance, and volume, in addition to further weakening of the sphincters and pelvic floor muscles. The average age of onset of symptoms is surprisingly young—51 years of age.

Many women with FI have multiple defects in their continence mechanisms, making it a very difficult condition to treat. This is one of the reasons why many treatments have previously failed, as they only work to address a single cause (e.g. sphincter tears or nerve damage). Conservative attempts to control fecal incontinence, including dietary changes and physical therapy have been largely unsuccessful.

More invasive approaches have been tried to statically reduce the size or change the angle of the anorectal canal. Such approaches include: injectable bulking agents—a substance that gets injected into the walls of the canal; sphincteroplasties—a surgical method of tightening the sphincter; and rings and slings—devices placed partially or all the way around the rectum. Such treatments have shown poor results, likely because they are fundamentally static devices and cannot achieve a dynamic and controllable function like a healthy sphincter. Devices such as American Medical System's Acticon Neosphincter address this problem by functioning as an artificial sphincter that the patient can control. The neosphincter consists of a cuff placed around the rectum, a patient-controlled pump implanted in the labia, and a reservoir implanted in the abdomen. Such devices have better

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dynamic range, but their invasive nature has led to infection, erosion, and removal rates. As a result, very few such procedures are performed. Therefore, a great need exists for a dynamic treatment to fecal incontinence that is not invasive.

U.S. Patent Application Publication No. 20060211911 to Jao, et al. discloses a vaginal insert having a cylindrical front projection **11** and a head **20** at the rear end thereof for holding by a person's hand. In use, and as shown in FIG. **6**, the person holds the head **20** and then inserts the cylindrical front projection **11** into the vagina **30** to push the rectovaginal septum **50** outward against the rectum **40**, thereby guiding accumulated excrement **70** back to the rectum **40**. The Jao, et al. device generally aids in the passage of stool, not prevention of stool passage. It demonstrates that rectal contents can be controlled intra-vaginally. However, it discusses nothing that would occlude the rectum to prevent stool. It also does not discuss something that would stay in the vagina in order to control stool passage. Further, it discusses nothing that could fit stably in the vagina in order to control the rectum.

U.S. Pat. No. 6,013,023 to Klingenstein discloses a device for controlling fecal incontinence of a hollow, tubular member **1** defining a longitudinal cavity **2** that terminates in a closed proximal end **3** and an expandable sheath **6**. Wings **13** can also assist in holding the device in place.

A major drawback of Klingenstein's device is the means provided for stabilizing the device, which is essential to carry out the desired functionality. Klingenstein describes wings external to the vagina, which would be uncomfortable and cumbersome for patients. He also describes device expansion as a means for securing the device. It was discovered in Applicants' cadaver studies, that an intra-vaginal device where securing relies on expansion is inherently unstable when the device is unexpanded. It was further discovered that when such devices transition from unexpanded to expanded states, their positioning and directionality is variable and unpredictable. This is especially problematic when the goal is to use the vaginal device to apply a directed force to the rectum. For one, if the device is inserted in an unexpanded state, it makes it difficult to reliably expand to apply a force on the right spot. Additionally, throughout the course of use, patients can wish to deflate, but not remove, the device for defecation or other activities when they feel active bowel control is not needed. In these cases, as is the case initially, the instability upon deflation would make it difficult to re-expand in the right position. An improvement to Klingenstein's device would be one that has a stabilization means that is intra-vaginal and does not rely on expansion of the device. This would allow comfortable, repeatable application of force to the same portion of a patient's posterior vagina.

Another drawback to the stability of Klingenstein's device is that it is a tubular device, more specifically defined as generally cylindrical. Applicants' reduction to practice has revealed that this type of shape does not stably rest in the vagina, especially if force is applied towards the recto-vaginal septum, as it tends to rotate. An improvement to the art is a device designed to prevent rotation around the axis formed by the distal and proximal ends of the device, such that it can remain in the appropriate position to exert a repeatable force on the proper part of the recto-vaginal septum.

Another major drawback of Klingenstein's device is that it lacks body means to allow easy force transfer from the vagina to the rectum. Applicants' experimentation has revealed the importance of the availability of redundant vaginal tissue to maintain force on the rectum. If a device is not designed to allow redundancy (or slack) in the vaginal wall in the area where the force is transmitted to the rectum, then the tension in the wall makes it difficult to transfer the force posteriorly.

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Klingenstein does not teach any art that would allow for such vaginal slack in the area where his device transmits force to the rectum. An improvement to the art would therefore describe a device that has a design to allow for sufficient slack to remain in the vaginal walls adjacent the force apply portion such that force is easily transmitted to the rectum.

There are a variety of pessaries in the prior art. These devices are usually indicated for the treatment of pelvic organ prolapse, in which they support organs, such as the uterus, from prolapsing into the vaginal canal. There are also other intra-vaginal devices in prior art for the purposes of birth control, urinary incontinence, and other conditions. These devices come in different shapes. Some have the ability to expand, but not in a directionally applied manner. None of these intra-vaginal devices are designed to be able to apply a directed force towards the rectum, let alone the ability to do so stably, repeatedly and with minimal force.

Therefore, there remains a need for a fecal incontinence device that can be inserted in the vagina and stably apply a force to the rectum in order to control the passage of stool. Such a device has not previously been conceived, and as a result there are no such devices in the market place and, more generally, no viable treatment for the millions of women suffering from fecal incontinence. Described below is a device for treating fecal incontinence, which explores the unique combination of stability and directed rectal occlusion.

#### SUMMARY OF THE INVENTION

The present invention provides for an intra-vaginal device for the control of stool passage, including a body mechanism for securing the device around the area of the pubic notch and in the area of the posterior fornix, the body mechanism including a force applying mechanism for reversibly applying a force to a posterior portion of the vagina to occlude the rectum.

The present invention provides for a method of controlling the passage of stool in a patient, by inserting an intra-vaginal device into the patient's vagina such that an anterior end rests around the pubic notch and a posterior end rests in the posterior fornix, exerting a force towards the posterior side of the vagina, preventing expansion of the patient's rectum with the force, impeding the passage of stool, and removing the force, allowing stool to pass.

The present invention provides for an intra-vaginal device, including a stabilizing body operatively connected to a rectal occluding member and including toggle means for toggling said occluding member between an occlusive and passive state.

The present invention provides for a method of controlling the passage of stool in a patient by inserting an intra-vaginal device into the patient's vagina, toggling an occluding member at the posterior end to an occlusive state, preventing expansion of the patient's rectum with the occluding member, impeding the passage of stool, and toggling the occluding member to a passive state, allowing stool to pass.

The present invention provides for an intra-vaginal device, including a stabilizing body for receiving an occluding member for controlling the passage of stool.

The present invention also provides for an occluding member for controlling the passage of stool, including a body and a securing mechanism for securing the occluding member to a dock on an intra-vaginal device.

The present invention provides for a method of controlling the passage of stool in a patient, by inserting a stabilizing body of an intra-vaginal device into the patient's vagina, inserting an occluding member in the vagina, docking the

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occluding member on the stabilizing body, preventing expansion of the patient's rectum with the occluding member, and impeding the passage of stool.

The present invention provides for an intra-vaginal device for the control of stool, including a stabilizing body including a force applying portion that produces minimal displacement adjacent to lateral walls of a patient's vaginal wall allowing for occlusion of the rectum by the force applying portion.

The present invention provides for a stabilizing mechanism for repeatedly contacting a force applying portion with a same area of an anterior rectum wall, the force applying portion being able to apply force and impede the passage of stool through the rectum.

The present invention provides for an intra-vaginal device including a stabilizing mechanism for stabilizing the device to prevent rotation and translation in the vagina, thereby allowing a portion of the device to reversibly apply force to the same area of the rectovaginal septum to control stool movement through the rectum.

The present invention provides for a method of controlling stool movement through the rectum, by stabilizing an intra-vaginal device and preventing rotation and translation in the vagina, reversibly applying force to the same area of the rectovaginal septum with the device, and controlling stool movement through the rectum.

The present invention provides for an intra-vaginal device, including a stabilizing mechanism for stabilizing the device to prevent rotation and translation in the vagina in a first and second state, wherein when in a first state, force is not applied to the rectovaginal septum (RVS) and, wherein when in a second state, force is applied to the RVS thereby allowing a portion of the device to reversibly apply force to the same area of the rectovaginal septum to control stool movement through the rectum.

The present invention provides for a method of controlling stool movement through the rectum, by stabilizing an intra-vaginal device and preventing rotation and translation in the vagina when the device is in a first and second state, wherein when in a first state, force is not applied to the rectovaginal septum (RVS) and, wherein when in a second state, force is applied to the RVS, reversibly applying force to the same area of the rectovaginal septum with the device, and controlling stool movement through the rectum.

The present invention provides for a device including a stabilizing mechanism for stabilizing the device in a body orifice and a force applying mechanism for applying force to an orifice wall, the stabilizing mechanism imparting minimal tension on the walls of the orifice proximate the force applying mechanism, such that the force applying mechanism can displace the orifice wall.

The present invention further provides for a method of controlling flow of a substance through a body orifice, by stabilizing a device and preventing rotation and translation in the body orifice, reversibly applying force to the same area of the body orifice with the device, and controlling the flow of the substance through the body orifice.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages of the present invention are readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIGS. 1A-1D are perspective, bottom, side, and front views of the intra-vaginal device;

FIGS. 2A-2B are cross-sectional views of the body showing the position of the device;

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FIG. 3A is an exploded view of the device and FIG. 3B shows a folded device for insertion;

FIGS. 4A-4E are top views of stabilizing body sizes;

FIGS. 5A-I are views of various stabilizing body profiles;

FIGS. 6A-6D show the application of force to the expanding member, and FIGS. 6E-6F show the expanding member with a supportive member;

FIGS. 7A-7G show cross-sectional views of the vagina and rectum with the effect of vaginal displacement due to shapes of intra-vaginal devices;

FIGS. 8A-8M show alternative stabilizing body and anterior end shapes;

FIGS. 9A-9C show the device including a cap with the inflation mechanism;

FIGS. 10A-10B are side views of the device with a spring in the expandable member;

FIGS. 11A-11B are side views of the device with a spring in the expandable member, FIGS. 11C-11D are side views of the device showing one method of operating the inflation mechanism, and FIGS. 11E-11F show views of the expandable member with reinforcements;

FIGS. 12A-12C show views of the device to accommodate a larger cervix;

FIGS. 13A and 13B are side views of the device with additional occlusion mechanisms;

FIGS. 14A-14G are side views of a second embodiment of the device; and

FIGS. 15A-15G are views of a third embodiment of the device;

FIGS. 16A-16E are views of the device with grips or suction mechanisms;

FIGS. 17A-17B are views of the device fitting with the cervix, and FIGS. 17C-17E are side views of the device collapsing and expanding;

FIGS. 18A-18B are perspective views of an adjustable expandable member;

FIGS. 19A-19D are views of the expandable member being adjustable angularly both in and out of the body;

FIGS. 20A-20G are side views of the device wherein the anterior end and posterior end are decoupled;

FIGS. 21A-21D are perspective views and top views of the device;

FIGS. 22A-22B are side views of the device wherein the expandable member 18 expands in an opposite direction;

FIGS. 23A-23C are views of latching mechanisms;

FIGS. 24A-24B are views of attaching mechanisms for maintaining the inflation mechanism in the vagina;

FIGS. 25A-25B are views of the inflation mechanism as a tube;

FIGS. 26A-26B are side views of a device with active contraction;

FIGS. 27A-27B are perspective views of the device with irreversible removal;

FIG. 28A is a side view of an external inflation mechanism, and FIGS. 28B-28D are views of the device with a mechanism for directing the inflation mechanism to a valve;

FIG. 29 is a side view of an electromagnetic inflation mechanism;

FIGS. 30A-30B are views of the device with a retractable inflatable mechanism;

FIGS. 31A-31C are views of different shaped expandable members, and FIGS. 31D-31G are views of the device with suction mechanisms;

FIGS. 32A-32B are views of the device with a bleed mechanism;

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FIGS. 33A-33B are side views of a threaded toggle mechanism, and FIG. 33C is a side view of a snap-fit locking mechanism;

FIGS. 34A-34B show the line formed between the anterior and posterior ends;

FIGS. 35A-35C are side views of the device with a single use reservoir; and

FIGS. 36A-36C are side views of the device with a single use syringe.

## DETAILED DESCRIPTION OF THE FIGURES

The present invention provides generally for an intra-vaginal device 10 that is used to control stool passage, generally shown in FIGS. 1A-1D. The intra-vaginal device 10 includes a stabilizing body 12 for securing the device around the area of the pubic notch and posterior fornix and for supporting a force-applying portion 18. The force applying portion 18 can reversibly apply a force to the recto-vaginal septum (the tissue separating the vagina from the rectum) which has the effect of inhibiting the passage of stool through the rectum. This force application can be as shown in FIGS. 2A and 2B, wherein the force application is made via a member expanding against the recto-vaginal septum.

Preferably, the device 10 is designed for the anterior region 14 to fit in the area of the pubic notch. The pubic notch is formed in the anterior vagina, resulting from the structure of the surrounding pelvic floor muscles, providing a stable anchoring point for the anterior end 14 of the device. Preferably, the posterior end 16 of the device 10 fits into the area of the posterior fornix. This is the deepest region of the vagina (i.e. the vaginal vault) behind the cervix. In patients without a cervix, e.g. those who have undergone a hysterectomy, the device still rests in the same area, which is the deepest extension of the vagina. A device designed to fit in this region has added security and stability. A more preferable embodiment is designed to fit in both of these areas to provide stability. A device designed for securing in the aforementioned locations will ensure that when placed properly, it rests outside of the region where the vagina is highly innervated, making the device comfortable for the patient. Additionally, the design of the preferred device, by engaging these locations, ensures easy repeatable positioning when the device is inserted, and further ensures positional certainty and stability such that when the device is inserted, it is in the correct position to apply force to the appropriate portion of the recto-vaginal septum, and can do so over multiple inflation/deflation cycles without the need for repositioning.

The force applying portion 18, is preferably an expandable member, and more preferably an inflatable member such as a balloon, though other mechanisms are considered below.

The inhibition of stool resulting from the application of force is due to the force the device applies to the rectum, which disallows the normal expansion of the rectal lumen, which normally occurs to accommodate stool. This action can be described as applying a force to deflect the recto-vaginal septum to compress the rectum, or as generally preventing the expansion of the rectum by applying a force to it. Alternatively, the force applying portion can reversibly apply a force against the vaginal wall opposite of the recto-vaginal septum, which would prevent stool passage by pressing the stabilizing body, or an additional expandable member, against the recto-vaginal septum.

The stabilizing body preferably includes a portion proximate to the force applying portion that has a narrow lateral

span, such that when inserted, there is minimal distention of, and tension in, the walls of the vagina proximate to the force applying portion.

The stabilizing body **12**, preferably has an anterior end **14** and a posterior end **16** operatively connected by a portion **20** or **12**, which has a narrow lateral span and includes the force applying member **18**, such that when inserted, the anterior end **14** preferably rests around the pubic notch and the posterior end **16** preferably rests in the posterior fornix of the vagina, thereby stabilizing and maintaining the position of the intra-vaginal device **10** while minimizing pressure or tension to the lateral walls of the vagina, as shown in FIGS. **2A** and **2B**. This portion of narrow lateral span can be considered as a central portion of the stabilizing body, or can also be considered as a posterior portion of the stabilizing body.

The preferred embodiment described above minimizes the imparting of tension in the lateral vaginal walls by having a narrow lateral span, especially in proximity to the force applying portion. In a more preferred embodiment, the width narrows from the anterior end **14** to the portion including the force applying portion **18** (FIGS. **1A** and **1B**), and also considered is a device that narrows from the posterior end **14** to the central portion (Insert FIG. **40A**). Alternatively, the anterior end, **14** and the posterior end **16** can be connected by a more generally elongate portion, such as a rod (FIG. **8**, item **12**), thus avoiding pressure application on the lateral walls.

The width of the expandable portion can be 1-6 cm, more preferably 3-4 cm. The length of the expandable portion can be 1-6 cm, more preferably 2-5 cm. The main body proximate to the expandable portion can be less than 7 cm and more preferably less than 5 cm in width to reduce tension in the vaginal walls.

It is important that the intra-vaginal device **10** not utilize lateral distention of the vagina for fixation when applying pressure to the rectum to occlude stool. FIG. **7A** shows a cross-section of the vagina and rectum, wherein the vagina has plenty of slack redundant tissue in folds along the wall. FIGS. **7B** and **7C** show an intra-vaginal device with a wider body that takes out the slack in the vagina walls, making it difficult to utilize the recto-vaginal septum to occlude the rectum. Since the device creates significant lateral distension on the adjacent wall, the wall loses its redundancy and elasticity and is not easily manipulated by the expandable portion. FIGS. **7D-E** show the intra-vaginal device **10** of the present invention, wherein the device **10** takes advantage of the vaginal redundancy to push on the rectum. In other words, sufficient slack is still present in the vagina once the device **10** has been inserted, allowing the vaginal walls to be manipulated such that the rectum is occluded. This configuration allows stability and comfort while providing the function of occluding the rectum.

Therefore, the present invention provides for an intra-vaginal device **10** for the control of stool, including a main body **12** having an anterior end **14** and a posterior end **16**, wherein the anterior end **14** and posterior end **16** are operatively interconnected by a portion or sides **20**, which include a force applying member **18**, such that the aforementioned portion or sides produce minimal displacement adjacent to lateral walls of a patient's vaginal wall allowing for occlusion of the rectum by the expandable member **18**.

In order to further prevent lateral pressure on the vaginal walls, the sides **20** can laterally narrow when the expandable member is expanded. As shown in FIG. **7E**, pressure "a" on the sides **20** when the expandable member expands can cause the sides **20** to narrow laterally. This is also shown in FIGS. **7F** and **7G**.

The stabilizing body **12** can also include extensions extending perpendicular to an axis formed by a line between the pubic notch and posterior fornix, wherein the extensions prevent rotation around the axis. The extensions can extend in a different direction as the direction of the force applying portion **18**. The extensions can be perpendicular to the direction of said force applying portion **18**. The stabilizing body **12** and the extensions can be a substantially planar structure.

The terms "occluding" or "occlude" as used herein, refer to restricting or obstructing the passage of stool through the rectum. The occlusion can be a full obstruction of the rectum, or it can be a partial obstruction. It is desired to prevent damage to the tissue separating the rectum from the vagina, herein referred to as the "recto-vaginal septum", so the recto-vaginal septum is not overly stretched, but merely held in place against, or displaced towards, the opposite side of the rectum and prevented from expanding in at least one direction to allow the normal passage of stool.

The term "toggling" or "toggle" as used herein, refer to the ability of an object (i.e. the occluding member **108** further described herein) to alternate between two or more positions. The toggling can be accomplished by mechanical or electronic mechanisms further described below.

The stabilizing body **12** of the device **10** can be made of wire forms **22** enclosed in tubing **24**, as shown in FIG. **3A**. The wire forms **22** can be in any suitable configuration, but preferably, there is a wire form **22** for each side of central portion **20**. In other words, preferably, the central portion **20** is two sides **20**, but a single central portion **20** can be used. Any suitable wire can be used that will provide enough strength to maintain the shape of the device. Alternatively, a polymeric reinforcement can be used in place of, or in conjunction with, the wire forms. The tubing **24** is preferably silicon, but other materials can be used that are biocompatible. The surface of the stabilizing body **12** can include grips **52** on its surface in order to stabilize the device against tissue that it contacts. The grips **52** are small enough and shaped so that the tissue is not damaged or irritated by use. The grips **52** can also be a suction mechanism such as pocks that hold the stabilizing body **12** in place with a vacuum, as shown in FIGS. **31D**, **31F**. The stabilizing body **12** can also be inflatable, in order to help with insertion and removal.

In a preferred embodiment, the stabilizing body **12** is generally narrow, with the posterior end **16** being approximately of the same width as the force applying portion **18** and in a rounded shape, and the anterior end **14** being slightly wider and in a squared shape in order to fit securely around the pubic notch, and further so as not to unduly take out the slack in the vagina walls. The widened anterior end **14** can be a surface that is curved to approximate the curvature of the pelvic floor muscles interfacing therewith, shown in FIGS. **8K-8M**. The roundness of the posterior end **16** also eases insertion and prevents irritation to the vaginal walls. The squareness (i.e. larger flat section before curving into the corners) of the anterior end **14** further helps in preventing the device **10** from rotating within the body. The lateral span of the portion **20** proximate to the force applying portion **18** can be slightly wider than a width of the force applying portion **18**.

The anterior end **14** and the posterior end **16** preferably include springs **26**, or other members that are at least in part flexible, that join the wire forms **22** in the stabilizing body **12** together. The springs **26** and the wire forms **22** can be operatively connected by any mechanism known in the art, including silicone, which can be overmolded over the wireforms. The springs **26** allow the device **10** to be folded along its length for easier insertion and return the device **10** to its open configuration once inside the vagina and in the preferred



position around the pubic notch and in the posterior fornix. The springs **26** allow the device **10** to conform more naturally to the contours of the vagina. The springs **26** can also or alternatively be located between the anterior end **14** and posterior end **16** along the stabilizing body **12** such that the ends **14**, **16** are decoupled from each other (as shown in FIGS. **20A-20G**). The springs **26** further prevent force being imparted on one end **14**, **16** from being directly transmitted to the other end **14**, **16**. For example, body forces due to the abdominal contents above the vagina, or forces due to a force applying portion **18** will have less of an effect on the stability of the anterior end **14** if they are connected by a flexible component. The wire forms **22** provide stiffness in the longitudinal direction. The folded configuration is shown in FIG. **3B**. Alternatively, the stabilizing body **12** can also be made out of memory materials, alloys, or a contiguous flexible polymer that can return to an open shape after being folded for insertion.

The device **10** can be manufactured according to methods known in the art. For example, silicon adhesive or heat bonding can be used in assembly, or the device **10** can be injection molded as one single piece. The stabilizing body **12** can be glued together or heat melded, and the force applying portion **18** can be injection molded.

The stabilizing body **12** can also be manufactured in various sizes and shapes as shown in FIGS. **4A-4D**. The central portion **20** of the device **10** can easily be shortened or lengthened to provide different sizes. The anatomy of every woman is different, and having various sizes and shapes available of the device **10** can allow for many different women to use the device **10**. A suitable device **10** can be determined by a trial and error method of insertion. Alternatively, a CAT scan can be performed or X-rays taken, or other medical imaging technologies (ultrasound, MRI) to measure the dimensions of the vagina and rectum, in order to choose a preexisting device **10** or to custom manufacture the device **10** for a particular body. Additionally, specific tools such as a highly adjustable device or device proxy can be used to determine the correct size and shape for a given patient.

The stabilizing body **12** can also be not completely straight when viewed from a sagittal plane, but include an upward angled or curved anterior end **14** (FIGS. **5A-E**), a stepped stabilizing body **12** (FIG. **5F**), a bowed stabilizing body **12** (FIG. **5G**), or an upward angled central portion of the stabilizing body **12** (FIGS. **5H-I**). In other words, the stabilizing body **12** can include a portion that raises above the line formed by the anterior end **14** and the posterior end **16** (this line is shown in FIGS. **34A-34B**). These different shapes of the stabilizing body **12** can aid in stability of the device **10** in different anatomies.

The force applying portion **18**, preferably in the form of an expandable member **18** and referred to as such herein interchangeably, at the posterior end **16** can be actuated between an expanded state and a contracted state in order to either prevent stool from passing through the rectum by pressing against the recto-vaginal septum and preventing the rectum from expanding to allow passage of stool (expanded state) or to allow stool to pass through the rectum (contracted state). The expandable member **18** is also preferably in the contracted state upon insertion, and can fold into the stabilizing body **12** and into itself for ease of insertion. However, the device **10** can also be inserted with the expandable member **18** at least partially expanded, and merely providing means for contracting the expandable member **18** (or allowing it to be compressed) to allow the passage of stool.

The expandable member **18** can be in various shapes and can include a domed portion that contacts the recto-vaginal

septum. The expandable member **18** can be wider at a terminal end **33** opposite to where it attaches to the stabilizing body **12** (FIG. **31A**), or can be narrow at its terminal end **33** (FIG. **31B**). The expandable member **18** can be curved (FIG. **31C**).

The expandable member **18** can be in the form of a balloon type portion. The balloon can have a permeability to allow for deflation over a pre-determined range of time. Other forms of the expandable member **18** can also be used. A surface of the expandable member **18** that contacts the vagina wall can include grips **52** for stabilization. The grips **52** are small enough and shaped so that they do not irritate or damage the tissue, and they can also be in the form of suction as described above.

The expandable member **18** can also provide partial, but not total occlusion. It can not require total or complete occlusion to prevent fecal excretion. Upon occlusion, it is preferred that as much function of the rectum is left as possible, but that the most compliant area of the recto-vaginal septum is engaged and only that area by the expandable member **18**. That is, the expandable member **18** should contact the rectum as low as possible to permit as much of the rectum to be functional for fecal storage, and yet it should contact the rectum high enough to provide effective contact to result in the occlusion. This location is preferably above the perineal body, which is bulkier and usually less compliant the recto-vaginal septum. Therefore, in order to provide the best positioning of the device **10**, the expandable member **18** can be manufactured at different positions along the posterior end **16** or along various portions of the stabilizing body **12** in order to fit different anatomies. The expandable member **18** can also be manually adjustable along the length of the posterior end **16**/stabilizing body **12**, which the physician can adjust to fit a patient (FIGS. **18A-18B**), with an adjusting mechanism **56**. Preferably, the expandable member **18** extends from the stabilizing body **12** at a non-zero angle with respect to a line formed by the anterior end **14** and the posterior end **16**. More preferably, the expandable member **18** contacts the rectum wall at a 45-135 degree angle. The expandable member **18** can be angularly adjustable with an angular adjustment mechanism **58** in order to ensure that it is targeting the appropriate part of an individual's anatomy, as shown in FIGS. **19A-19D**.

An inflation mechanism **28** is included on the expandable member **18** for expansion and contraction (deflation), which can be reversible or irreversible. The inflation mechanism **28** can be permanently attached to the expandable member **18** and remain in the vagina or extend outside of the vagina (further described below) to expand and contract the expandable member **18**. The inflation mechanism **28** can be in the form of a tube (FIG. **25A-25B**) that creates a leak when pulled that creates irreversible deflation. The tube can also be used with a tool **64** for widening the tube for emptying or filling the tube. Alternatively, the inflation mechanism **28** can be removably attached and can be attached only when the expandable member **18** needs to be expanded or contracted. The inflation mechanism **28** can include a flange at the end attached to the device **10**, and located within the device **10**, in order to prevent the inflation mechanism **28** from being pulled out of the device **10**. The inflation mechanism **28** can be manually operated, such as by pulling on the inflation mechanism **28** to contract or expand the expandable member **18** (shown in FIGS. **11C** and **11D**), using a hand pump, reservoir, syringe, or it can be electronically operated by a remote control outside of the body. In this case, the expandable member **18** and device **10** include appropriate electronics. The inflation mechanism **28** can be a single use device that is thrown out after use. For example, the single use device can

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be an air-filled pouch or reservoir **70** that can only be compressed once to fill the device **10**, shown in FIGS. **35A-35C**, through a one-way valve **68**. After inflation, the reservoir **70** is removed and the one-way valve **68** remains. Alternatively, it can be a locking syringe **72** that only compresses once through the one-way valve **68**, shown in FIGS. **36A-36C**. After inflation, the syringe **72** is removed and the one-way valve **68** remains.

The inflation mechanism **28** can also be an electromagnetic system, shown in FIG. **29**, that can be activated externally by a switch that turns on an electromagnet causing the expandable member **18** to expand or contract. For example, one electromagnet can be on the top side **32** of the expandable member **18** and another electromagnet can be located opposite thereto on a bottom side **33**, and they can be toggled between attracting each other (contracted state) and repelling each other (expanded state). Appropriate electronics and leads can be included to operate the magnets. The inflation mechanism **28** can also be water, air, a self-curing polymer, or a material that reacts to moisture or heat found in the vagina.

The expandable member **18** can be naturally in an expanded state and must be actively contracted, or alternatively, the expandable member **18** can be naturally in a contracted state and must be actively expanded. Specific examples of the active contraction mechanisms are springs inside the expandable member **18** (further described below), an elastic mechanism attached to the expandable member **18**, or an elastic material. Alternatively, the expandable member **18** can include a mechanism for expanding automatically, such as elastics and a one-way valve for allowing air to enter as the expandable member expands. An example of an irreversibly expandable device **10** with active contraction is shown in FIGS. **26A-26B**, wherein the inflation mechanism **28** is a zip-tie-like chord that can be pulled, ratcheting the expandable member **18** down.

The inflation mechanism **28** can further include a cap or a valve **34** on a distal end **36** that is accessible outside of the body, as shown in FIGS. **9A-9C**. By use of the cap **34**, the expandable member **18** can be inflated fully or partially prior to insertion of the device **10** in the body. The cap **34** can be removed or actuated to deflate the expandable member **18** and allow stool to pass through the rectum. To enhance deflation, the fluid in the expandable member **18** can be actively expelled by means of a pump. The expandable member **18** can then be expanded again, either by a mechanism as described above, or the expandable member **18** can expand on its own due to the stiffness of the material it is made from.

The expandable member **18** can include a spring **38** that self-expands the expandable member **18**, as shown in FIGS. **10A** and **10B**, and **11A** and **11B**. In other words, the expandable member **18** can be self expandable by various means, requiring active deflation or contraction to allow fecal passage. In this embodiment, the user would not have to actively inflate or expand the device during use. Rather, the user would actively deflate or contract the device to allow for fecal elimination.

The inflation mechanism **28** can include a string **40** accessible to the user outside of the body that can be pulled to collapse the spring **38** and allow stool to pass. After the string **40** is released, the spring **38** pushes the expandable member **18** back into an expanded state naturally. In other words, this expandable member **18** is generally in an expanded state and must be actively contracted. The spring **38** can also work with the cap **34** described above instead of the string **40**. A tube or a wire can also be used in place of the string **40**. The spring **38** can also be controlled by a component separate from the device **10**, such as a rod, a threaded member, or a keyed

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member, that is insertable into the vagina for engagement with the spring **38**. Preferably, these mechanisms that extend outside of the vagina are of minimal size so as not to cause discomfort of the user. This can include tubes that are collapsible to a generally flat profile and can be opened with the insertion of an additional component to aid in inflation/deflation (shown in FIGS. **25A-25B**).

The inflation mechanism **28** can further include a latching mechanism **60** for holding the inflation mechanism **28** (preferably in the form of a tube) in a retracted position inside the vagina, shown in FIGS. **23A-23C**. Users can prefer the comfort of this option as opposed to allowing an inflation mechanism **28** to extend outside the vagina. The latching mechanism **60** can include a first component towards a distal end of the inflation mechanism and a second component on the stabilizing body **12**, the expandable member **18**, or the inflation mechanism **28** proximate to the stabilizing body **12**. The latching mechanism **60** can be a mechanical latch (such as a clip, FIG. **23C**), a magnetic latch (FIG. **23B**), or a hook and loop latch. The inflation mechanism **28** can be retractable into the stabilizing body **12** or the expandable member **18** when not in use (FIGS. **30A-30B**). The latching mechanisms **60** can also be features attached to the inflation mechanism **28** that, based on their size and shape, are retained above the introitus. These features can also facilitate the retrieval of the inflation mechanism **28** when inflation/deflation is required.

The inflation mechanism **28** can further include an attachment mechanism **62** towards a distal end of the inflation mechanism **28** for pulling it or the device **10** downward, or for tucking and maintaining the inflation mechanism **28** inside the vagina. The attachment mechanism **62** can be a flexible or non-flexible ring or loop, as shown in FIGS. **24A-24B**.

The inflation mechanism **28** can be external to the vagina and engage the intra-vaginal device **10** to permit the exchange of fluid with the expandable member **18** (FIG. **28A**). In this case, the inflation mechanism is preferably a syringe, or pump that interfaces with the intra-vaginal device **10**. The inflation mechanism **28** can interface with a valve **68** or system of valves on the stabilizing body **12** or the expandable member **18**. The stabilizing body **12** or the expandable member **18** can include a mechanism **66** for directing the inflation mechanism **28** to the valve **68** or system of valves, such as a funnel structure (FIGS. **28C-28D**), or a magnetic attraction (FIG. **28B**).

The expandable member **18** can further include a supportive member **30**, such as a cut silicon sheet or a molded silicon member, in order to prevent the expandable member **18** from tilting due to force from the presence of stool in the rectum. FIGS. **6A-6D** show what can happen to the expandable member **18** with force applied thereto, i.e. the expandable member **18** can begin to tilt upwards into the stabilizing body **12**, and not completely block the passage of stool. Therefore, a supportive member **30** can be attached between the expandable member **18** and the stabilizing body **12** so that tilting is prevented. The supportive member **30** can cover the entire surface of a top side **32** of the expandable member **18**, as in FIG. **6E**, or the supportive member **30** can be only a strip covering a portion of the top side **32**, as in FIG. **6F**. The supportive member **30** can also be integrated directly in the top side **32** of the expandable member **18**. The supportive member **30** can also cover a portion or an entire inner space of the stabilizing body **12** (as shown in FIGS. **21A-21D**). The supportive member **30** can be made of any suitable material that can withstand the force of the stool on the expandable member **18** and maintain the expandable member **18** in position.

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The expandable member **18** can further include reinforcements **42** circumferentially around the surface, such as string, stiffer material than the expandable member **18** itself, or a thicker portion of the same material, as shown in FIGS. 11E-11F. The reinforcements **42** can aid in stretching the expandable member **18** in a preferential direction, i.e. at the 45-135 degree angle to the rectum wall. The supportive member **30** can also include reinforcements **42** for preventing deflection such as embedded fibers, plastic, or metal.

The expandable member **18** can also support anatomical features external to the vaginal cavity to prevent their prolapse into the vaginal cavity.

In order to ensure a comfortable fit for users who have a more prominent cervix (FIG. 12A), the top side **32** of the expandable member **18** and/or supportive member **30** can be bowed into the expandable member **18**, accomplished by an indentation or a hole, as shown in FIGS. 12B-12C. Any suitable amount of bowing can be used and this aspect can be designed for a particular user by trial and error fitting, or medical imaging analysis of the vagina.

FIGS. 17A and 17B also show the device **10** with multiple sides **20** or rails of the stabilizing body **12** extending from the anterior end **14** to the posterior end **16** that anchor the cervix and also prevent rotation along the length of the device **10**. FIG. 17C shows that in this form, the stabilizing body **12** can be collapsed to a smaller profile for insertion, such as by pulling on the ends **14**, **16** of the device **10**. The spring forces in the sides **20** can also cause the device **10** to spring back to the larger profile (FIG. 17D). The device **10** can also be forced into the larger profile, such as by a member **54** that can be pulled, pulling the ends **14**, **16** of the device **10** together (FIG. 17E).

Various aspects of the device **10** can also serve to support other organs around the vagina to help alleviate symptoms of prolapse.

The stabilizing body **12** can include an anterior end **14** with other shapes, projections, or space-occupying features in order to keep the device **10** stable in the vagina, but not cause lateral displacement of the vagina walls. For example, the stabilizing body **12** can include a ring-shaped anterior end **14'**, shown in FIGS. 8A-8B. The stabilizing body **12** does not have two sides of a central portion **20** in this case but rather a single central portion **20** connects the anterior end **14'** and the posterior end **16**. The anterior end **14'** can also be a cross-shape, or anchor shape as shown in FIGS. 8C-8D. The anterior end **14'''** can also be a multi-pronged anchor shape, as shown in FIGS. 8E-8F. The anterior end **14''''** can be a soft or spongy portion, e.g. tampon-like material, that prevents the device **10** from sliding out in FIG. 8G and also expands as it absorbs body fluids such as water. The anterior end **14''''** can be a disc or diaphragm that is a generally perpendicular planar body to act as a plug to keep the device **10** inside the introitus as shown in FIG. 8H-8I. The disc **14'41** can be a soft material such as a compliant cushion so that it can deform during insertion, and can also provide suction. Drainage holes **44** can be included as well as a removal mechanism **46**, such as a string or soft silicon, which can extend outside of the vagina to facilitate removal **15**. The disc **14''''** can include an embedded member which can be pulled to reversibly or irreversibly disrupt the mechanical integrity of the disc **14''''** such that the device **10** is easily removed. The removal mechanism **46** can be included on any embodiment as well, and can be a ring, string, wire, flap, rod, or tube.

The anterior end **14''''** can be mechanisms to secure the device **10** in the vagina as well as allow for easy removal, such as a spring and tab as shown in FIG. 8J. The tab can be depressed and cause the spring to be contracted, allowing for

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removal of the device **10**. Additionally, the anterior end **14** can be shaped to approximate the curvature of the pelvic floor muscles it interacts with.

Another important aspect of the device **10** is that it has positional stability and rotational stability within the vagina. The positional stability is provided by points of contact of the device **10** with the vagina, most notably the anterior end **14** with the pubic notch and the posterior end **16** with the posterior fornix. The expandable member **18** can further provide stability with contact with the wall of the vagina. It is this positional stability that allows the stabilizing body **12** to be designed in different shapes as long as these points of contact remain. Rotational stability is provided as well by the contact of the anterior end **14** with the pubic symphysis and the posterior end **16** with the posterior fornix. This rotational stability limits the rotation of device **10** when the expandable member **18** is expanded. Additionally, rotation around the device's anterior-posterior axis is prevented by extensions off of this axis as described above, and more specifically by a generally planar structure. Even more specifically, this rotation is prevented by the additional width of the stabilizing body **12** at either end of the device **10**. The expandable member **18** contacts the same part of the vagina wall to occlude the rectum every time that the device **10** is used.

Therefore, the present invention provides for a stabilizing mechanism for repeatably contacting the force applying portion **18** with a same area of an anterior rectum wall, the force applying portion **18** being able to inhibit the ability of the rectum to expand to allow stool to pass through. These aspects of the invention are critical for assuring maximum comfort and reliability of results for the user.

The stabilizing mechanism can be longitudinal members (i.e. sides **20** and the anterior end **14** and posterior end **16**) that form a three-dimensional structure that can change from a smaller profile for insertion to a larger profile for stability. This ability to change the form is described above with the springs **26**. The longitudinal members can exert a spring force biasing them towards the larger profile. A mechanical mechanism can be used to secure the longitudinal members in the larger profile, such as a compression mechanism for drawing ends of the longitudinal members close together, i.e. a string, wire, tube, chain, flexible rod, or threaded member.

An additional embodiment utilizes suction forces on a body for stabilization means to allow repeatable positioning and repeatable contact to the recto-vaginal septum (FIGS. 16A-16E). These bodies can be different shapes other than the preferred shape described herein, such as, but not limited to, a cube, wedge, or pyramid, provided they meet the described criteria for stabilization and force application.

In an additional embodiment, the stabilizing mechanism can be secured to a body through surgical attachments to one or more walls of the vagina as described above. The stabilizing mechanism can also include adhesive to secure in the body.

More generally, the device **10** can substantially maintain a single shape that applies force to the rectum. This force can be modulated by changing the position of the device **10** inside the vagina, or by removal and insertion of the device **10**.

The present invention also provides for an intra-vaginal device **10** including a stabilizing mechanism as described above for stabilizing the device **10** to prevent rotation and translation in the vagina, thereby allowing a portion of the device **10** to reversibly apply force to the same area of the rectovaginal septum to control stool movement through the rectum. The importance of applying pressure on the same area of the rectum has been described above.

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The present invention provides for a method of controlling stool movement through the rectum, by stabilizing the intra-vaginal device **10** described above and preventing rotation and translation in the vagina, reversibly applying force to the same area of the rectovaginal septum with the device **10**, and controlling stool movement through the rectum. The force can be applied with the force applying portion **18** as described above.

The present invention also provides for an intra-vaginal device **10**, including a stabilizing mechanism for stabilizing the device **10** to prevent rotation and translation in the vagina in a first and second state, wherein when in a first state, force is not applied to the rectovaginal septum (RVS) and, wherein when in a second state, force is applied to the RVS thereby allowing a portion of the device to reversibly apply force to the same area of the rectovaginal septum to control stool movement through the rectum.

The present invention provides for a method of controlling stool movement through the rectum, including the steps of stabilizing the intra-vaginal device **10** described above and preventing rotation and translation in the vagina when the device **10** is in a first and second state, wherein when in a first state, force is not applied to the rectovaginal septum (RVS) and, wherein when in a second state, force is applied to the RVS, reversibly applying force to the same area of the rectovaginal septum with the device, and controlling stool movement through the rectum.

There can be other mechanisms used along with the device **10** in order to achieve rectal occlusion. For example, a magnet **48** can be surgically implanted in the posterior rectal wall in order to interact with a corresponding magnet **48'** on the device **10**, such as at the bottom of the expanding member **18** as shown in FIG. **13A**. The magnets **48**, **48'** can be electro-magnets and can be externally controlled, allowing them to interact with each other to occlude the rectum or to let stool pass. Alternatively, magnet **48'** can be simply implanted in the vagina wall opposite the posterior rectum wall without the device **10** to achieve the same results. Also, a mass-occupying agent **50** can be injected into the posterior rectal wall, as shown in FIG. **13B**, so that when combined with the device **10**, better occlusion of the rectum occurs. Preferably, the mass-occupying agent **50** is directly opposite to the expanding member **18** and interacts therewith. The device **10** can be used with an implanted sling that pulls the rectum anteriorly.

The present invention provides for a method of controlling the passage of stool in a patient, including the steps of inserting the intra-vaginal device **10** into the patient's vagina such that the anterior end **14** rests around the pubic notch and the posterior end **16** rests in the posterior fornix, exerting a force towards the posterior side of the vagina, preventing expansion of the patient's rectum with the force, impeding the passage of stool, and removing the force, allowing stool to pass. By performing this method, the patient can use the device **10** to prevent stool from passing or allow stool to pass through the rectum. When inserting the device **10**, the sides **20** can narrow by the operation of the springs **26** at the anterior end **14** and posterior end **16** for easier insertion. Then the sides **20** return to their normal open position once the device **10** is positioned around the pubic notch and in the posterior fornix. Preferably, the force applying portion **18** exerts the force and moves the anterior wall of the rectum. As described above, the force applying portion **18** can be expanded manually or electronically. As the force applying portion **18** expands, because there is slack in the vagina walls, the force of expansion is directed against the rectum, and passage of stool is inhibited. The force can be exerted substantially above the perineal body. The prevention can be an occlusion of the rectum. When it is

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desired that stool pass through the rectum, the expandable member **18** is contracted (there can be recovery of the expandable member through various mechanisms described above) and the walls of the rectum are allowed to accommodate stool normally.

In an alternative embodiment, device **100** includes a stabilizing body **102** having an anterior end **104** and a posterior end **106**, the posterior end **106** operatively connected to an occluding member **108** and including a toggle mechanism **110** for toggling the occluding member **108** between an occlusive and passive state. Essentially, the occluding member **108** can change orientation between a rectally occlusive state, shown in FIG. **14A**, to a passive state to allow stool to pass through the rectum, shown in FIG. **14B**. The device **100** is generally the same as device **10** described above, except that instead of expanding, the occluding member **108** toggles positions. The device **100** preferably is situated in the vagina such that the anterior end **104** rests around the pubic notch and the posterior end **106** rests in the posterior fornix.

The toggle mechanism **110** can be any mechanism known in the art to toggle positions of the occluding member **108**. For example, the toggle mechanism **110** can be a hinge or a flexible joint that joins the occluding member **108** to the stabilizing body **102**. The toggle mechanism **110** can be a translatable occlusive member such as a slidable occlusive member, or an occlusive member with multiple locked positions such as snap-fit locking mechanisms. (FIG. **33C**). The toggle mechanism **110** can also be a threaded member that can be extended or retracted by engaging one or more threads, shown in FIGS. **33A-33B**. Preferably, the toggle mechanism **110** includes a method of locking the occluding member **108** when occlusion is desired and so that movement of the occluding member **108** does not occur. A latch mechanism **112** can be used to lock the occluding member **108** in the occluding position as shown in FIGS. **14C-14D** anywhere on the occluding member **108** and stabilizing body **102**, such as on a side opposite to the toggle mechanism **110**. The toggle mechanism **110** can include a control string **114**, as shown in FIGS. **14E-14F**, or any other control component that extends outside of the vagina such as a wire, tube, lever, or threaded component. The control string **114** can be attached anywhere appropriate on the occluding member **108**. Under tension of the control string **114**, the occlusive member **108** cannot move and is locked in place in an occluding position. When tension in the control string **114** is released, the occlusive member **108** is free to rotate and moves to a passive position to let stool through the rectum. The occluding member **108** can have an altered or more tapered shape on a side opposite to the toggle mechanism **110** in order to have a more comfortable fit when in the passive position, as shown in FIG. **14G**.

In an alternate embodiment, the intra-vaginal device can be toggle between and occluding and non-occluding state by removing the device in its entirety from the vagina.

Therefore, the present invention provides for a method of controlling the passage of stool in a patient, including the steps of inserting the intra-vaginal device **100** into the patient's vagina such that the anterior end **104** rests around the pubic notch and the posterior end **106** rests in the posterior fornix, toggling the occluding member **108** at the posterior end **106** to an occlusive state, preventing expansion of the patient's rectum with the occluding member **108**, impeding the passage of stool, and toggling the occluding member **108** to a passive state, allowing stool to pass. This method is generally performed as the method described above, except that instead of expanding the expandable member **18**, the occluding member **108** is toggled between an occlusive state

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to occlude the passage of stool in the rectum and a passive state to allow the passage of stool. The toggling step can further include shifting the occluding member 110 to different snap-fit positions, (FIG. 33C) sliding the occluding member 110 to different position, or engaging threaded components on the occluding member 110 for moving the occluding member 110. The toggling step can be performed by actuating the control string 114 above, or a wire, tube, lever, or threaded component. These components for actuation can be outside of the vagina. The toggling step can also include locking the occluding member 108 with the latch mechanism 112 described above. The preventing step can also include occluding the rectum.

In another embodiment, shown in FIGS. 15A-15G, device 200 includes a stabilizing body 202 having an anterior end 204 and posterior end 206, the posterior end 206 including magnets 210 that act as a docking mechanism for receiving an occluding member 208 having magnets 210'. In this device 200, the stabilizing body 202 and occluding member 208 are separate pieces. Preferably, the stabilizing body 202 is generally as described above and the same shape, with the addition of magnets 210 in the posterior end 206 for receiving the occluding member 208. The device 200 preferably is situated in the vagina such that the anterior end 204 rests around the pubic notch and the posterior end 206 rests in the posterior fornix. The occluding member 208 has corresponding magnets 210' in areas that line up with the magnets 210 of the posterior end 206. The occluding member 208 can be a rigid material, or it can be semi-rigid and expandable, or compliant as described above. The occluding member 208 can include an insertion mechanism 212 that can be used for ease of insertion into the vagina and can aid in stabilizing the occluding member 208 within the stabilizing body 202. When in place, the insertion mechanism 212 can reach from the occluding member 208 to the anterior end 204, as shown in FIG. 15D. The stabilizing body 202 can alternatively, or in addition to the magnets 210, include a mechanical lock 214. In this case, the occluding member 208 also includes a matching mechanical lock 214' to secure the occluding member 208 in the stabilizing body 202. The docking mechanism can also be shape fit, i.e. the shape of the device 200 itself that allows for docking. When it is desired to prevent the passage of stool, the occluding member 208 can be inserted (and optionally expanded) and held in place by the magnets 210, 210' and/or the mechanical lock 214, 214'. The occluding member 208 can be adjustably docked along the length of the stabilizing body 202. The occluding member 208 can also cause the stabilizing body 202 to apply force. When it is desired to let stool pass, the occluding member 208 is removed (and optionally contracted). The occluding member 208 can further include mechanisms for removal, as described above, such as string, a tube, wire, a ring, a tab, a chain, or a flexible rod. In this embodiment, the stabilizing body 202 can be surgically implanted in the vagina and remain inside, whereas the occluding member 210 can be inserted or removed as desired, shown in FIG. 15E. In this case, the occluding member 210 can be disposable whereas the stabilizing body 202 is more of a permanent device. The present invention also provides for the occluding member 210 itself for controlling the passage of stool, wherein the occluding member 210 is a body and includes a securing mechanism for securing the occluding member 210 to a dock on the device 200.

Therefore, present invention further provides for a method of controlling the passage of stool in a patient, including the steps of inserting the stabilizing body 202 of the intra-vaginal device 200 into the patient's vagina, inserting the occluding member 208 in the vagina, docking the occluding member

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208 on the stabilizing body 202, preventing expansion of the patient's rectum with the occluding member 208, and impeding the passage of stool. Preferably, the anterior end 204 rests around the pubic notch and the posterior end 206 rests in the posterior fornix. The docking of the occluding member 208 can occur by the interaction of the magnet

Therefore, present invention further provides for a method of controlling the passage of stool in a patient, including the steps of inserting the stabilizing body 202 of the intra-vaginal device 200 into the patient's vagina, inserting the occluding member 208 in the vagina, docking the occluding member 208 on the stabilizing body 202, preventing expansion of the patient's rectum with the occluding member 208, and impeding the passage of stool. Preferably, the anterior end 204 rests around the pubic notch and the posterior end 206 rests in the posterior fornix. The docking of the occluding member 208 can occur by the interaction of the magnets 210, 210' and/or the mechanical locks 214, 214' as described above. The docking step can include placing the occluding member 208 such that it is compressed between the stabilizing body 202 and vaginal wall. The preventing step can include occluding the rectum. The method can further include the step of undocking and removing the occluding member 208 from the vagina, allowing stool to pass. Stool can be allowed to pass also by changing the position of the occluding member 208 instead of removal.

Any part of the devices 10, 100, 200 can be disposable and made of a material that allows for flushing down the toilet after a single use. For example, the expandable member 18/occlusive member 108, 208 can be irreversibly deflated upon activation of a feature. For example, a bleed in the form of a tube/string 40 can be pulled which trips a valve or detaches the tube 40 from the expandable member 18 or generally causes leakage of fluid, causing it to deflate, as shown in FIGS. 32A-32B. This allows the patient to pass stool and the device 10 is removed and disposed of. Any of the mechanical parts of the expandable member 18, such as the spring 38 can be actuated to irreversible collapse. Another example is the removal of the device 10 causes the stabilizing body 12 to irreversibly collapse or lose structural integrity, shown in FIGS. 27A-27B. The device 10, 100, 200 can be encased in an applicator, which is inserted in the vagina and upon actuation, the device expands into proper shape and rectal occlusion. A disposable pump (e.g. a bag filled with an amount of air) can be included with the device 10, 100, 200, which can be squeezed after insertion and then can be torn off and disposed of. The removal of the device 10 can also cause an irreversible mechanical compromising of the device 10 that prevents future use.

The present invention also provides more generally for a device including a stabilizing body for stabilizing the device in a body orifice and a force applying portion for applying force to an orifice wall, the stabilizing body imparting minimal tension on the walls of the orifice proximate to the force applying portion, such that the force applying portion can displace the orifice wall. In other words, the device 10 of the present invention is not limited to use in the vagina for rectal occlusion, but can be made in different sizes for different applications throughout the body. The stabilizing body can narrow proximate to the force applying portion to minimize tension on the orifice wall. A region proximate to the force applying portion can be narrower than one or both ends of the device. The force applying portion can reversibly apply force. The applied force can be imparted on a neighboring structure.

Therefore, the present invention also provides for a method of controlling flow of a substance through a body orifice, by stabilizing a device 10 and preventing rotation and translation

in the body orifice, reversibly applying force to the same area of the body orifice with the device 10, and controlling the flow of the substance through the body orifice. This method can be performed as described above but it can be used in any part of the body, not just in the vagina for rectal occlusion.

The invention is further described in detail by reference to the following experimental examples. These examples are provided for the purpose of illustration only, and are not intended to be limiting unless otherwise specified. Thus, the invention should in no way be construed as being limited to the following examples, but rather, should be construed to encompass any and all variations which become evident as a result of the teaching provided herein.

#### EXAMPLE 1

##### Cadaver 1 Summary:

It was demonstrated herein the potential for an expanding intra-vaginal device by applying a force to the rectum to inhibit the passage of stool. However, it was demonstrated that existing devices were not capable of doing this and that there are certain key features necessary to achieve stool inhibition. For example, Inflatoball is an intra-vaginal pessary that expands non-directionally as a large rounded shape inside the vagina. Even at large volumes and pressures, the Inflatoball did not occlude the rectum because it did not direct the expansion. Similarly, other pessaries and intra-vaginal devices also were not able to occlude the rectum. The LiveSure V1, which consists of a tubular, cylindrical body with an attached inflatable portion that can expand to occlude the rectum, was used. However, it was unable to occlude the rectum because it had no means for stabilization. Upon inflation of the expandable portion, the main body would rotate or translate so that the expansion was no longer directed towards the rectum. The procedure was then repeated, with the LiveSure V1 held manually in place so that it would not rotate or translate. Upon doing so, the device was able to direct a force towards the rectum, but it required a very large force and placed a lot of strain on the rectovaginal septum in order to occlude the rectum, and even then, it could only partially occlude the rectum. The reason for this was that the design did not allow for enough slack in the tissue of the vaginal wall in order to deflect it posteriorly. Therefore, a large force needed to be used in order to stretch the tissue of the septum back towards the rectum—something that would likely be painful and physiologically damaging in a live patient. Both such problems of stability and high pressure requirements are also expected to occur with the embodiment described by Klingenstein. This highlighted the need for a design that was stable and could occlude the rectum without undo stress on the surrounding tissue. Results are shown in TABLE 1.

TABLE 1

Device	Digital Rectal Exam
Inflatoball	Not Occluded
Other pessaries	Not Occluded
*LiveSure V1	Not Occluded
*LiveSure V1 (Held in place and under high pressure and force)	Partial Occlusion

\*LiveSure V1 consists of a tubular, cylindrical body with an attached inflatable portion that can expand to occlude the rectum.

##### Cadaver 2 Summary:

This experiment sought to demonstrate a design that would allow for a stable positioning of the device. LiveSure V3 was tested. This device consisted of a planar, ring-shaped base. It

was also designed to fit so that the posterior end fit into the region of the posterior fornix and the anterior end fit into the pubic notch. From this position there was an attached inflatable member that expanded from the planar body at approximately a 90 degree angle. This design was stable and did not rotate or translate when the expandable member was repeatedly inflated and deflated. However, upon inflation, the device was not able to occlude the rectum. This lack of occlusion resulted from the fact that the width of the stabilizing base stretched the vaginal tissue taught adjacent to the expandable portion, thereby eliminating the slack in the tissue necessary to deflect the tissue posteriorly. This study demonstrated the importance of stabilization feature and a shape that fits in the regions of the posterior fornix and notch of the pelvic floor. However, it also demonstrated that these features were not sufficient to allow for rectal occlusion. The results suggested that a device design with a base that is narrower in the region where expansion would occur would allow the RVS to remain slack such that an expandable member in the vagina could occlude the rectum.

##### Cadaver 3 Summary:

This study confirmed the results of Cadaver 2, wherein the LiveSure V3 fit stably but was not able to occlude the rectum. The LiveSure V5 was tested. This device shared the features of planarity and anchoring points in the posterior fornix and pubic notch with the LiveSure V3, however it narrowed in the base in the region proximate the expandable portion. In this manner, it was able to occlude the rectum with minimal force. In fact, there was almost a 1:1 transfer of force applied in the vagina and force felt in the rectum. This demonstrates that very little force was being placed on the rectovaginal septum—preventing stress and strain on the tissue while still being able to occlude the rectum. This was achieved because in its unexpanded state, the narrower profile allowed for extra slack in the vaginal walls that could then be taken up when the device expanded posteriorly.

##### Cadaver 4 Summary:

This confirmed the findings from Cadaver 3.

##### Discussion:

Cadaver 1 demonstrated the possibility of occluding the rectum with a vaginal device, but it lacked stability and directional expansion, and required high pressure and stretch to the tissue. Cadaver 2 demonstrated stability and directionality but tautness of the tissue prevented rectal occlusion. Cadaver 3 was successful in all three criteria. Cadaver 4 reaffirmed the results in Cadaver 3.

The LiveSure design in cadaver 4 demonstrated the functionality that we desire for treating fecal incontinence. It was able to occlude the rectum without stretching the RVS or generating excessive pressure in the LiveSure. It also maintained a stable and repeatable orientation, and expansion of the members was always directed towards the RVS. This design was based on the iterative feedback from our other cadaver experiments, discussions with physicians (urogynecologists, gynecologists, and colorectal surgeons), and literature. It required the development of unique, and key-enabling features not present in the prior art. Such features are described in detail in the specification and claims below.

#### EXAMPLE 2

The following are manufacturing instructions for assembling the device.

Apply Silicone Adhesive to Springs.

Insert Wire forms into Springs and cure adhesive.

Insert assembly into outer tubing.

Bond free ends of tubing together and cure adhesive.

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Bond inflation tube and balloon bottom to balloon, cure assembly.

Bond balloon assembly to base assembly and cure.

Throughout this application, various publications, including United States patents, are referenced by author and year and patents by number. Full citations for the publications are listed below. The disclosures of these publications and patents in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

The invention has been described in an illustrative manner, and it is to be understood that the terminology which has been used is intended to be in the nature of words of description rather than of limitation.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims, the invention can be practiced otherwise than as specifically described.

What is claimed is:

1. An intravaginal device for the control of stool passage of a female user, the device comprising:

a reversibly extendable force applying portion having an extended state and a nonextended state; and an intravaginal stabilizing body supporting the force applying portion, the stabilizing body extending in a longitudinal direction and in a lateral direction that is substantially perpendicular to the longitudinal direction, the stabilizing body having a laterally narrower portion and a laterally wider portion, and the greatest lateral extent of the force applying portion being narrower than the greatest lateral extent of the stabilizing body,

wherein the stabilizing body is sized and configured to fit entirely within a vaginal cavity of the user with the longitudinal extent of the stabilizing body extending substantially along a length of the vaginal cavity to hold the force applying portion in contact with the user's recto-vaginal septum to control the passage of stool through a rectum of the user.

2. The device of claim 1, wherein the device comprises a first engagement surface adapted to engage the vagina in the area of the pubic notch and a second engagement surface adapted to engage the vagina in the area of the posterior fornix.

3. The intravaginal device of claim 2 wherein the device is adapted to securely engage the pubic symphysis and the posterior fornix.

4. The device of claim 2, wherein the force applying portion is adapted to contact the recto-vaginal septum above the perineal body when the first engagement surface engages the vagina in the area of the pubic notch and the second engagement surface engages the vagina in the area of the posterior fornix.

5. The device of claim 2 wherein the stabilizing body comprises a ring, the first engagement surface being disposed on a first end of the ring and the second engagement surface being disposed on a second end of the ring opposite the first side.

6. The device of claim 1 wherein the force applying portion has a width of 1-6 cm and a length of 1-6 cm.

7. The device of claim 6 wherein the force applying portion has a width of 3-4 cm and a length of 2-5 cm.

8. The device of claim 1 wherein the device is adapted to prevent rotation about an axis extending from an anterior end to a posterior end of the device during the extended and non-extended states.

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9. The device of claim 1 wherein the stabilizing body has a lateral span that is narrower in proximity to the force applying portion than in a region not in proximity to the force applying portion.

10. The device of claim 1 wherein the force applying portion is disposed in a proximal portion of the stabilizing body.

11. The device of claim 1 wherein the stabilizing body is generally planar, the force applying portion extending out of the plane of the stabilizing body.

12. The device of claim 1 wherein the force applying portion comprises a supportive member adapted to prevent deflection of the force applying portion.

13. The device of claim 1 wherein the device is configured to support the force applying portion against the recto-vaginal septum above the perineal body in the extended and non-extended states.

14. The device of claim 1, wherein the force applying portion is foldable into the stabilizing body.

15. The device of claim 1, wherein the force applying portion includes a spring adapted to expand the force applying portion.

16. The device of claim 1, wherein the device comprises a portion adapted to accommodate a cervix.

17. The device of claim 1, wherein the device includes suction features adapted to stabilize the device within the vagina.

18. The device of claim 1, wherein the force applying portion includes an electromagnetic system.

19. The device of claim 1, wherein the force applying portion is positioned along the laterally narrower portion of the stabilizing body.

20. The device of claim 19, wherein the laterally narrower portion of the stabilizing body comprises a proximal portion of the stabilizing body that is configured to be positioned in a superior portion of the vaginal cavity.

21. The device of claim 19, wherein the greatest lateral extent of the force applying portion is supported by the laterally narrower portion of the stabilizing body.

22. The device of claim 19, wherein substantially the entire force applying portion is positioned along the laterally narrower portion of the stabilizing body.

23. The device of claim 1, wherein the device is sized and configured such that tension in the vaginal wall in a superior portion of the vagina is less than tension in the vaginal wall in an inferior portion of the vaginal cavity when the device is disposed in the vaginal cavity and the force applying portion is in the nonextended state.

24. The device of claim 1, wherein the force applying portion is positioned along a proximal portion of the stabilizing body that is configured to be positioned in a superior portion of the vaginal cavity.

25. The device of claim 24, wherein the stabilizing body is substantially planar.

26. The device of claim 1, wherein the stabilizing body is in the form of one or more wire forms enclosed in tubing.

27. The device of claim 26, wherein the stabilizing body further comprises one or more springs.

28. The device of claim 1, wherein the stabilizing body includes a first wire form that extends along a first side of the stabilizing body, a second wire form that extends along a second side of the stabilizing body, and a spring that connects an end of the first wire form to an end of the second wire form.

29. The device of claim 28, wherein the spring is configured to allow the stabilizing body to be folded along a length of the device.

30. The device of claim 1, wherein the force applying portion comprises a balloon.

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31. The device of claim 1, wherein the device is sized and configured to fit entirely within the vaginal cavity of the user.

32. A method of selectively occluding a rectum to inhibit stool passage in a female user, the method comprising:

inserting an intra-vaginal device into the user's vagina;

stably supporting a force applying portion of the device against a recto-vaginal septum of the user while the force applying portion is in a nonextended state and slack is maintained in a region of a vaginal wall of the user adjacent the nonextended force applying portion;

extending the force applying portion to an extended state to apply a force with the force applying portion against the recto-vaginal septum while stably supporting the force applying portion against the recto-vaginal septum to impede passage of stool through the rectum of the user; and

after extending the force applying portion to the extended state to apply the force with the force applying portion against the recto-vaginal septum, reducing the force sufficiently to permit stool to pass through the rectum.

33. The method of claim 32 wherein the device further comprises a stabilizing body, and stably supporting the force applying portion of the device against the recto-vaginal septum comprises engaging the stabilizing body with the vagina in the area of the pubic notch and in the area of the posterior fornix.

34. The method of claim 32 further comprising, after reducing the force sufficiently to permit stool to pass through the rectum, maintaining the force applying portion against the recto-vaginal septum above the perineal body.

35. The method of claim 32, wherein the device comprises an intravaginal stabilizing body having a laterally narrower portion and a laterally wider portion, and the force applying portion is positioned along the laterally narrower portion of the stabilizing body.

36. The method of claim 35, wherein the laterally narrower portion of the stabilizing body comprises a proximal portion of the stabilizing body that is configured to be positioned in a superior portion of the vaginal cavity.

37. The method of claim 35, wherein the greatest lateral extent of the force applying portion is supported by the laterally narrower portion of the stabilizing body.

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38. The method of claim 35, wherein substantially the entire force applying portion is positioned along the laterally narrower portion of the stabilizing body.

39. The method of claim 32, wherein the stabilizing body is substantially planar.

40. An intravaginal device for the control of stool passage of a female user, the device comprising:

a reversibly extendable force applying portion having an extended state and a nonextended state; and

an intravaginal stabilizing body supporting the force applying portion, the stabilizing body having a laterally narrower portion and a laterally wider portion, and the greatest lateral extent of the force applying portion being narrower than the greatest lateral extent of the stabilizing body,

wherein the stabilizing body has a lateral span that is narrower in proximity to the force applying portion than in a region not in proximity to the force applying portion, and the stabilizing body is sized and configured to fit entirely within a vaginal cavity of the user to hold the force applying portion in contact with the user's recto-vaginal septum to control the passage of stool through a rectum of the user.

41. An intravaginal device for the control of stool passage of a female user, the device comprising:

a reversibly extendable force applying portion having an extended state and a nonextended state; and

an intravaginal stabilizing body supporting the force applying portion, the stabilizing body having a laterally narrower portion and a laterally wider portion, and the greatest lateral extent of the force applying portion being narrower than the greatest lateral extent of the stabilizing body,

wherein the stabilizing body is sized and configured to fit entirely within a vaginal cavity of the user to hold the force applying portion in contact with the user's recto-vaginal septum to control the passage of stool through a rectum of the user, and the device is sized and configured such that tension in the vaginal wall in a superior portion of the vagina is less than tension in the vaginal wall in an inferior portion of the vaginal cavity when the device is disposed in the vaginal cavity and the force applying portion is in the nonextended state.

\* \* \* \* \*



UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 9,072,578 B2  
APPLICATION NO. : 13/635598  
DATED : July 7, 2015  
INVENTOR(S) : Steven Lawrence Herbowy, Miles Harris Rosen and Jacob Samuel Brenner

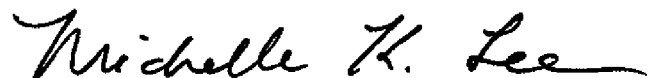
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the specification

Column 1, line 7, delete "Phasc" and insert -- Phase --.

Signed and Sealed this  
Twenty-fourth Day of November, 2015

A handwritten signature in black ink that reads "Michelle K. Lee". The signature is written in a cursive style with a long, sweeping underline.

Michelle K. Lee  
*Director of the United States Patent and Trademark Office*